

US011026791B2

(12) **United States Patent**  
**Genovese et al.**

(10) **Patent No.:** **US 11,026,791 B2**  
(45) **Date of Patent:** **Jun. 8, 2021**

(54) **FLEXIBLE CANOPY VALVE REPAIR SYSTEMS AND METHODS OF USE**

(58) **Field of Classification Search**  
CPC ..... A61F 2/2454; A61F 2/2457; A61F 2/246;  
A61F 2/2463

(71) Applicant: **MEDTRONIC VASCULAR, INC.**,  
Santa Rosa, CA (US)

See application file for complete search history.

(72) Inventors: **Matthew Genovese**, Windsor, CA (US);  
**Jeffrey Sandstrom**, Scandia, MN (US);  
**Russell Pribanic**, Roxbury, CT (US);  
**Thomas Mcpeak**, Caledonia, MN (US);  
**Vania Lee**, Circle Pines, MN (US);  
**Dermot O'Brien**, Galway (IE); **James Calvin Allan**, Boise, ID (US)

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,165,183 A 12/2000 Kuehen et al.  
6,260,552 B1 7/2001 Mortier et al.  
(Continued)

FOREIGN PATENT DOCUMENTS

WO 2012068541 A2 5/2012  
WO 2017115123 A1 7/2017

(73) Assignee: **MEDTRONIC VASCULAR, INC.**,  
Santa Rosa, CA (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 55 days.

OTHER PUBLICATIONS

PCT/US2019/022680, The International Search Report and Written Opinion, dated Aug. 9, 2019, 17pgs.

(21) Appl. No.: **16/352,963**

*Primary Examiner* — Suba Ganesan

(22) Filed: **Mar. 14, 2019**

(74) *Attorney, Agent, or Firm* — Meddler Ferro Woodhouse & Mills PLLC

(65) **Prior Publication Data**

US 2019/0290431 A1 Sep. 26, 2019

**Related U.S. Application Data**

(60) Provisional application No. 62/645,306, filed on Mar. 20, 2018.

(51) **Int. Cl.**

**A61F 2/24** (2006.01)  
**A61B 17/04** (2006.01)  
**A61B 17/00** (2006.01)

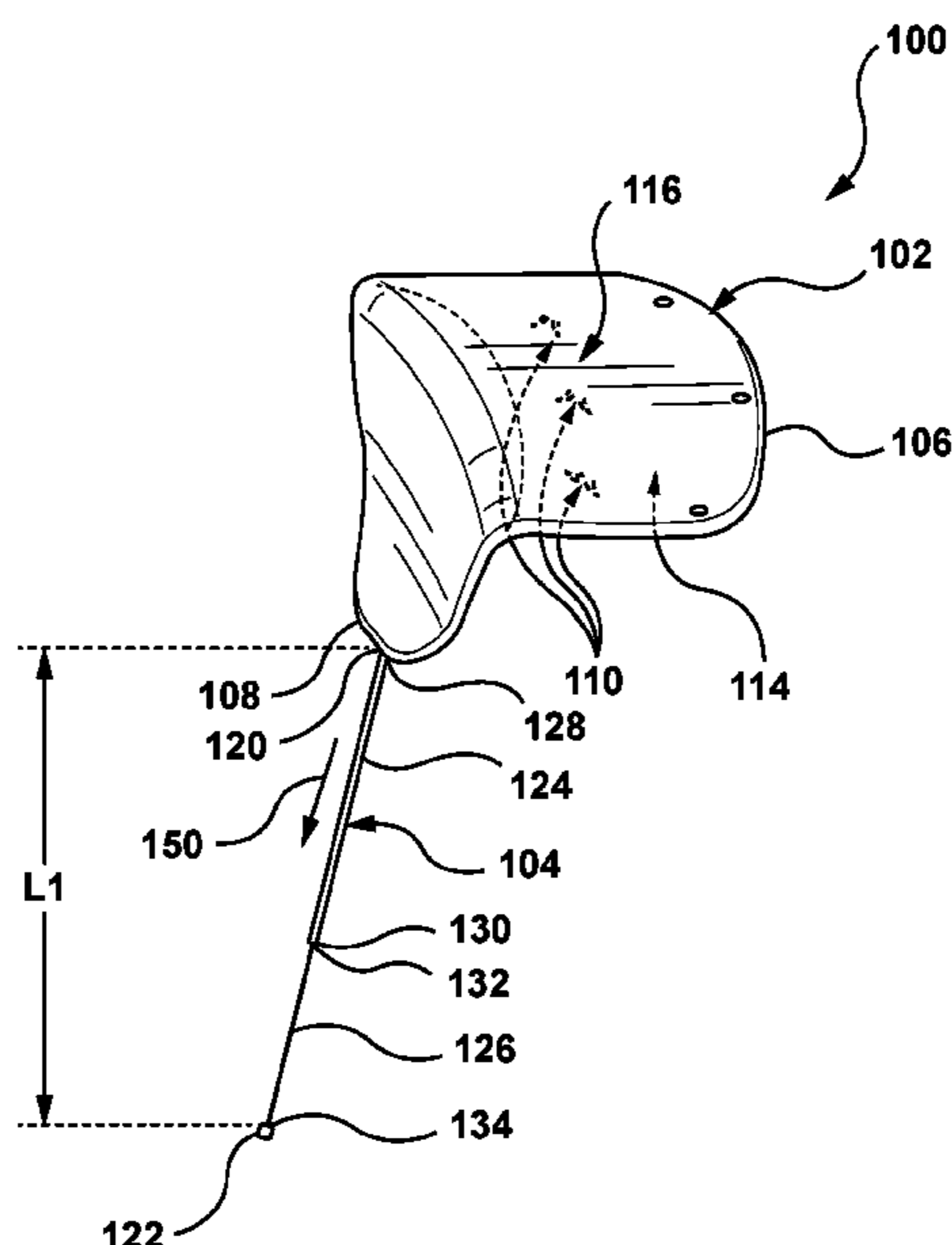
(57) **ABSTRACT**

A system for treating valvular regurgitation in a heart valve includes a flexible canopy and an elongated tether including an elastic portion and an inelastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is coupled to an annulus of the heart valve and a distal end of the elongated tether is coupled to a ventricle. The flexible canopy is configured to overlay a first native leaflet of the heart valve, and tension on the elongated tether is applied and/or adjusted to prevent the first leaflet from prolapsing, to maximize coaptation of the flexible canopy with a second native leaflet of the heart valve, and to minimize regurgitation of the heart valve.

(52) **U.S. Cl.**

CPC ..... **A61F 2/2454** (2013.01); **A61F 2/2412** (2013.01); **A61F 2/2457** (2013.01);  
(Continued)

**20 Claims, 17 Drawing Sheets**



## (52) U.S. Cl.

CPC ..... *A61F 2/2463* (2013.01); *A61B 17/0401*  
(2013.01); *A61B 2017/00243* (2013.01); *A61F*  
*2230/0095* (2013.01); *A61F 2250/0018*  
(2013.01)

## (56)

## References Cited

## U.S. PATENT DOCUMENTS

6,269,819 B1	8/2001	Oz et al.	7,112,207 B2	9/2006	Allen et al.
6,312,447 B1	11/2001	Grimes	7,112,219 B2	9/2006	Vidlund et al.
6,332,893 B1	12/2001	Mortier et al.	7,122,043 B2	10/2006	Greenhalgh et al.
6,355,030 B1	3/2002	Aldrich et al.	7,125,420 B2	10/2006	Rourke et al.
6,402,781 B1	6/2002	Langberg et al.	7,166,126 B2	1/2007	Spence et al.
6,406,420 B1	6/2002	McCarthy et al.	7,166,127 B2	1/2007	Spence et al.
6,419,696 B1	7/2002	Ortiz et al.	7,179,282 B2	2/2007	Alferness et al.
6,461,366 B1	10/2002	Seguin	7,179,291 B2	2/2007	Rourke et al.
6,537,314 B2	3/2003	Langberg et al.	7,186,264 B2	3/2007	Liddicoat et al.
6,575,971 B2	6/2003	Hauck et al.	7,189,199 B2	3/2007	McCarthy et al.
6,602,288 B1	8/2003	Cosgrove et al.	7,192,442 B2	3/2007	Solem et al.
6,619,291 B2	9/2003	Hlavka et al.	7,192,443 B2	3/2007	Solem et al.
6,626,930 B1	9/2003	Allen et al.	7,211,110 B2	5/2007	Rowe et al.
6,629,534 B1	10/2003	St. Goar et al.	7,226,467 B2	6/2007	Lucatero et al.
6,656,221 B2	12/2003	Taylor et al.	7,229,469 B1	6/2007	Witzel et al.
6,676,702 B2	1/2004	Mathis	7,247,134 B2	7/2007	Vidlund et al.
6,689,164 B1	2/2004	Seguin et al.	7,270,676 B2	9/2007	Alferness et al.
6,695,866 B1	2/2004	Kuehen et al.	7,288,097 B2	10/2007	Seguin
6,702,826 B2	3/2004	Liddicoat et al.	7,291,168 B2	11/2007	Macoviak et al.
6,706,065 B2	3/2004	Langberg et al.	7,296,577 B2	11/2007	Lashinski et al.
6,709,456 B2	3/2004	Langberg et al.	7,300,462 B2	11/2007	Swinford et al.
6,718,985 B2	4/2004	Hlavka et al.	7,309,354 B2	12/2007	Mathis et al.
6,719,767 B1	4/2004	Kimblad	7,311,728 B2	12/2007	Solem et al.
6,723,038 B1	4/2004	Schroeder et al.	7,311,729 B2	12/2007	Mathis et al.
6,743,239 B1	6/2004	Keuhn et al.	7,311,731 B2	12/2007	Lesniak et al.
6,746,471 B2	6/2004	Mortier et al.	7,314,485 B2	1/2008	Mathis
6,752,813 B2	6/2004	Goldfarb et al.	7,316,706 B2	1/2008	Bloom et al.
6,764,510 B2	7/2004	Vidlund et al.	7,351,259 B2	4/2008	Swinford et al.
6,770,083 B2	8/2004	Seguin	7,351,260 B2	4/2008	Nieminen et al.
6,790,231 B2	9/2004	Liddicoat et al.	7,357,815 B2	4/2008	Shaoulian et al.
6,793,673 B2	9/2004	Kowalsky et al.	7,361,190 B2	4/2008	Shaoulian et al.
6,797,001 B2	9/2004	Mathis et al.	7,364,588 B2	4/2008	Mathis et al.
6,797,002 B2	9/2004	Spence et al.	7,373,207 B2	5/2008	Lattouf
6,800,090 B2	10/2004	Alferness et al.	7,377,941 B2	5/2008	Rhee et al.
6,805,711 B2	10/2004	Quijano et al.	7,381,210 B2	6/2008	Zarbatany et al.
6,810,882 B2	11/2004	Langberg et al.	7,381,220 B2	6/2008	Macoviak et al.
6,824,562 B2	11/2004	Mathis et al.	7,396,364 B2	7/2008	Moaddeb et al.
6,840,246 B2	1/2005	Downing	7,404,824 B1	7/2008	Webler et al.
6,875,224 B2	4/2005	Grimes	7,431,692 B2	10/2008	Zollinger et al.
6,890,353 B2	5/2005	Cohn et al.	7,431,726 B2	10/2008	Spence et al.
6,908,478 B2	6/2005	Alferness et al.	7,442,207 B2	10/2008	Rafiee
6,913,608 B2	7/2005	Liddicoat et al.	7,452,375 B2	11/2008	Mathis et al.
6,926,715 B1	8/2005	Hauck et al.	7,464,712 B2	12/2008	Oz et al.
6,926,730 B1	8/2005	Nguyen et al.	7,473,274 B2	1/2009	Sater
6,949,122 B2	9/2005	Adams et al.	7,485,143 B2	2/2009	Webler et al.
6,960,229 B2	11/2005	Mathis et al.	7,500,989 B2	3/2009	Solem et al.
6,962,605 B2	11/2005	Cosgrove et al.	7,503,931 B2	3/2009	Kowalsky et al.
6,964,683 B2	11/2005	Kowalsky et al.	7,503,932 B2	3/2009	Mathis et al.
6,964,684 B2	11/2005	Ortiz et al.	7,507,252 B2	3/2009	Lashinski et al.
6,966,926 B2	11/2005	Mathis	7,509,959 B2	3/2009	Oz et al.
6,976,995 B2	12/2005	Mathis et al.	7,510,576 B2	3/2009	Langberg et al.
6,978,176 B2	12/2005	Lattouf	7,510,577 B2	3/2009	Moaddeb et al.
6,986,775 B2	1/2006	Morales et al.	7,513,908 B2	4/2009	Lattouf
6,989,028 B2	1/2006	Lashinski et al.	7,527,646 B2	5/2009	Rahdert et al.
6,997,951 B2	2/2006	Solem et al.	7,527,647 B2	5/2009	Spence
7,004,176 B2	2/2006	Lau	7,534,204 B2	5/2009	Starksen et al.
7,004,958 B2	2/2006	Adams et al.	7,534,260 B2	5/2009	Lattouf
7,011,669 B2	3/2006	Kimblad	7,536,228 B2	5/2009	Shaolian et al.
7,011,682 B2	3/2006	Lashinski et al.	7,559,936 B2	7/2009	Levine et al.
7,037,334 B1	5/2006	Hlavka et al.	7,563,267 B2	7/2009	Goldfarb et al.
7,044,967 B1	5/2006	Solem et al.	7,563,273 B2	7/2009	Goldfarb et al.
7,052,487 B2	5/2006	Cohn et al.	7,569,062 B1	8/2009	Kuehen et al.
7,070,618 B2	7/2006	Streeter	7,588,582 B2	9/2009	Ancora
7,077,861 B2	7/2006	Spence	7,591,826 B2	9/2009	Alferness et al.
7,077,862 B2	7/2006	Vidlund et al.	7,604,646 B2	10/2009	Goldfarb et al.
7,083,628 B2	8/2006	Bachman	7,608,091 B2	10/2009	Goldfarb et al.
7,090,695 B2	8/2006	Solem et al.	7,608,120 B2	10/2009	Adams et al.
7,094,244 B2	8/2006	Schreck	7,628,797 B2	12/2009	Tieu et al.
			7,635,329 B2	12/2009	Goldfarb et al.
			7,635,386 B1	12/2009	Gammie
			7,635,387 B2	12/2009	Reuter et al.
			7,637,945 B2	12/2009	Solem et al.
			7,637,946 B2	12/2009	Solem et al.
			7,655,015 B2	2/2010	Goldfarb et al.
			7,655,040 B2	2/2010	Douk et al.
			7,666,193 B2	2/2010	Starksen et al.
			7,666,204 B2	2/2010	Thornton et al.
			7,666,224 B2	2/2010	Vidlund et al.
			7,674,287 B2	3/2010	Alferness et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

7,682,319 B2	3/2010	Martin et al.	8,142,494 B2	3/2012	Rahdert et al.
7,682,369 B2	3/2010	Seguin	8,147,542 B2	4/2012	Maisano et al.
7,695,510 B2	4/2010	Bloom et al.	8,163,013 B2	4/2012	Machold et al.
7,695,512 B2	4/2010	Lashinski et al.	8,172,856 B2	5/2012	Eigler et al.
7,699,892 B2	4/2010	Rafiee et al.	8,172,898 B2	5/2012	Alferness et al.
7,704,277 B2	4/2010	Zakay et al.	8,182,529 B2	5/2012	Gordon et al.
7,713,298 B2	5/2010	Shaoulian et al.	8,187,207 B2	5/2012	Machold et al.
7,717,954 B2	5/2010	Solem et al.	8,187,266 B2	5/2012	Dickens et al.
7,722,523 B2	5/2010	Mortier et al.	8,187,299 B2	5/2012	Goldfarb et al.
7,722,668 B2	5/2010	Moaddeb et al.	8,187,323 B2	5/2012	Mortier et al.
7,736,388 B2	6/2010	Goldfarb et al.	8,202,315 B2	6/2012	Hlavka et al.
7,744,609 B2	6/2010	Allen et al.	8,211,171 B2	7/2012	Kim et al.
7,744,611 B2	6/2010	Nguyen et al.	8,216,230 B2	7/2012	Hauck et al.
7,753,858 B2	7/2010	Starksen et al.	8,216,256 B2	7/2012	Raschdorf et al.
7,753,922 B2	7/2010	Starksen	8,216,302 B2	7/2012	Wilson et al.
7,753,923 B2	7/2010	St. Goar et al.	8,216,303 B2	7/2012	Navia
7,753,924 B2	7/2010	Starksen et al.	8,226,709 B2	7/2012	Groothuis et al.
7,758,595 B2	7/2010	Allen et al.	8,226,711 B2	7/2012	Mortier et al.
7,758,596 B2	7/2010	Oz et al.	8,241,304 B2	8/2012	Bachman
7,758,637 B2	7/2010	Starksen et al.	8,241,351 B2	8/2012	Cabiri
7,758,639 B2	7/2010	Mathis	8,252,050 B2	8/2012	Maisano et al.
7,766,812 B2	8/2010	Schroeder et al.	8,262,724 B2	9/2012	Seguin et al.
7,785,366 B2	8/2010	Maurer et al.	8,277,502 B2	10/2012	Miller et al.
7,794,496 B2	9/2010	Gordon et al.	8,287,555 B2	10/2012	Starksen et al.
7,803,187 B2	9/2010	Hauser	8,287,557 B2	10/2012	To et al.
7,806,928 B2	10/2010	Rowe et al.	8,303,608 B2	11/2012	Goldfarb et al.
7,811,296 B2	10/2010	Goldfarb et al.	8,303,622 B2	11/2012	Alkhatib
7,814,635 B2	10/2010	Gordon et al.	8,323,334 B2	12/2012	Deem et al.
7,828,841 B2	11/2010	Mathis et al.	8,328,798 B2	12/2012	Witzel et al.
7,828,842 B2	11/2010	Nieminen et al.	8,333,777 B2	12/2012	Schaller et al.
7,828,843 B2	11/2010	Alferness et al.	8,343,173 B2	1/2013	Starksen et al.
7,837,728 B2	11/2010	Nieminen et al.	8,343,174 B2	1/2013	Goldfarb et al.
7,837,729 B2	11/2010	Gordon et al.	8,353,956 B2	1/2013	Miller et al.
7,857,846 B2	12/2010	Alferness et al.	8,357,195 B2	1/2013	Kuehn
7,871,368 B2	1/2011	Zollinger et al.	8,361,086 B2	1/2013	Allen et al.
7,871,433 B2	1/2011	Lattouf	8,382,829 B1	2/2013	Call et al.
7,883,538 B2	2/2011	To et al.	8,388,680 B2	3/2013	Starksen et al.
7,887,552 B2	2/2011	Bachman	8,409,273 B2	4/2013	Thornton et al.
7,887,582 B2	2/2011	Mathis et al.	8,425,504 B2	4/2013	Orton et al.
7,914,544 B2	3/2011	Nguyen et al.	8,439,971 B2	5/2013	Reuter et al.
7,922,762 B2	4/2011	Starksen	8,449,606 B2	5/2013	Eliassen et al.
7,927,370 B2	4/2011	Webler et al.	8,454,656 B2	6/2013	Tuval
7,931,684 B2	4/2011	Cosgrove et al.	8,454,683 B2	6/2013	Rafiee et al.
7,935,146 B2	5/2011	Langberg et al.	8,460,370 B2	6/2013	Zakay et al.
7,938,827 B2	5/2011	Hauck et al.	8,460,371 B2	6/2013	Hlavka et al.
7,942,927 B2	5/2011	Kaye et al.	8,470,028 B2	6/2013	Thornton et al.
7,942,928 B2	5/2011	Webler et al.	8,475,472 B2	7/2013	Bachman
7,955,384 B2	6/2011	Rafiee et al.	8,486,136 B2	7/2013	Maurer et al.
7,981,020 B2	7/2011	Mortier et al.	8,500,761 B2	8/2013	Goldfarb et al.
7,981,123 B2	7/2011	Seguin	8,500,800 B2	8/2013	Maisano et al.
7,988,725 B2	8/2011	Gross et al.	8,506,623 B2	8/2013	Wilson et al.
7,988,726 B2	8/2011	Langberg et al.	8,506,624 B2	8/2013	Vidlund et al.
7,993,397 B2	8/2011	Lashinski et al.	8,518,107 B2	8/2013	Tsukashima et al.
7,998,151 B2	8/2011	St. Goar et al.	8,523,881 B2	9/2013	Cabiri et al.
8,016,882 B2	9/2011	Macoviak et al.	8,540,620 B2	9/2013	Mortier et al.
8,029,565 B2	10/2011	Lattouf	8,545,414 B2	10/2013	Fitzgerald et al.
8,043,368 B2	10/2011	Crabtree	8,545,553 B2	10/2013	Zipory et al.
8,052,592 B2	11/2011	Goldfarb et al.	8,551,161 B2	10/2013	Dolan
8,057,493 B2	11/2011	Goldfarb et al.	8,579,967 B2	11/2013	Webler et al.
8,062,313 B2	11/2011	Kimblad	8,579,968 B1	11/2013	Shannon et al.
8,062,358 B2	11/2011	Mathis et al.	8,591,460 B2	11/2013	Wilson et al.
8,066,766 B2	11/2011	To et al.	8,608,797 B2	12/2013	Gross et al.
8,070,746 B2	12/2011	Orton et al.	8,632,585 B2	1/2014	Seguin et al.
8,070,805 B2	12/2011	Vidlund et al.	8,641,727 B2	2/2014	Ancora
8,075,616 B2	12/2011	Solem et al.	8,647,254 B2	2/2014	Callas et al.
8,092,363 B2	1/2012	Leinsing et al.	8,663,322 B2	3/2014	Keränen
8,092,525 B2	1/2012	Eliassen et al.	8,690,858 B2	4/2014	Machold et al.
8,096,985 B2	1/2012	Legaspi et al.	8,690,939 B2	4/2014	Miller et al.
8,100,964 B2	1/2012	Spence	8,709,074 B2	4/2014	Solem et al.
8,109,984 B2	2/2012	Solem et al.	8,715,342 B2	5/2014	Zipory et al.
8,123,703 B2	2/2012	Martin et al.	8,721,665 B2	5/2014	Oz et al.
8,128,691 B2	3/2012	Keränen	8,728,097 B1	5/2014	Sugimoto et al.
8,133,239 B2	3/2012	Oz et al.	8,734,467 B2	5/2014	Miller et al.
8,133,272 B2	3/2012	Hyde	8,734,505 B2	5/2014	St. Goar et al.
8,142,493 B2	3/2012	Spence et al.	8,740,918 B2	6/2014	Seguin
			8,740,920 B2	6/2014	Goldfarb et al.
			8,753,373 B2	6/2014	Chau et al.
			8,758,257 B2	6/2014	Cecere et al.
			8,758,393 B2	6/2014	Zentgraf

(56)

## References Cited

## U.S. PATENT DOCUMENTS

8,758,432 B2	6/2014	Solem et al.	9,198,757 B2	12/2015	Schroeder et al.
8,771,292 B2	7/2014	Allen et al.	9,216,018 B2	12/2015	Sutherland et al.
8,777,966 B2	7/2014	Dale et al.	9,226,787 B2	1/2016	Merryman et al.
8,778,016 B2	7/2014	Janovsky et al.	9,226,825 B2	1/2016	Starksen et al.
8,778,017 B2	7/2014	Eliassen et al.	9,232,942 B2	1/2016	Seguin et al.
8,784,482 B2	7/2014	Rahdert et al.	9,232,998 B2	1/2016	Wilson et al.
8,784,483 B2	7/2014	Navia	9,237,886 B2	1/2016	Seguin et al.
8,790,394 B2	7/2014	Miller et al.	9,254,141 B2	2/2016	Morris et al.
8,795,298 B2	8/2014	Hernlund et al.	9,259,218 B2	2/2016	Robinson
8,795,352 B2	8/2014	O'Beirne et al.	9,259,261 B2	2/2016	Boronyak et al.
8,808,368 B2	8/2014	Maisano et al.	9,259,317 B2	2/2016	Wilson et al.
8,821,570 B2	9/2014	Dumontelle et al.	9,265,608 B2	2/2016	Miller et al.
8,845,717 B2	9/2014	Khairkhahan et al.	9,271,833 B2	3/2016	Kim et al.
8,845,723 B2	9/2014	Spence et al.	9,277,994 B2	3/2016	Miller et al.
8,852,213 B2	10/2014	Gammie et al.	9,282,964 B1	3/2016	Cohen et al.
8,858,622 B2	10/2014	Machold et al.	9,301,842 B2	4/2016	Bielefeld
8,858,623 B2	10/2014	Miller et al.	9,314,242 B2	4/2016	Bachman
8,864,822 B2	10/2014	Spence et al.	9,320,600 B2	4/2016	Nieminen et al.
8,888,843 B2	11/2014	Khairkhanan et al.	9,326,857 B2	5/2016	Cartledge et al.
8,888,844 B2	11/2014	Eliassen et al.	9,345,470 B2	5/2016	Tuval
8,894,705 B2	11/2014	Eliassen et al.	9,351,830 B2	5/2016	Gross et al.
8,911,461 B2	12/2014	Traynor et al.	9,358,111 B2	6/2016	Spence et al.
8,911,494 B2	12/2014	Hammer et al.	9,358,112 B2	6/2016	Hlavka et al.
8,920,322 B2	12/2014	Mansi et al.	9,370,424 B2	6/2016	Call et al.
8,926,695 B2	1/2015	Gross et al.	9,393,080 B2	7/2016	Zentgraf et al.
8,926,696 B2	1/2015	Cabiri et al.	9,402,721 B2	8/2016	Buchbinder et al.
8,926,697 B2	1/2015	Gross et al.	9,408,695 B2	8/2016	Mathis et al.
8,932,348 B2	1/2015	Solem et al.	9,414,852 B2	8/2016	Gifford et al.
8,938,283 B2	1/2015	Zentgraf et al.	9,414,918 B2	8/2016	Chau et al.
8,940,042 B2	1/2015	Miller et al.	9,414,921 B2	8/2016	Miller et al.
8,940,044 B2	1/2015	Hammer et al.	9,421,098 B2	8/2016	Gifford et al.
8,945,177 B2	2/2015	Dell et al.	9,421,099 B2	8/2016	Dolan
8,945,211 B2	2/2015	Sugimoto	9,427,237 B2	8/2016	Oz et al.
8,951,285 B2	2/2015	Sugimoto et al.	9,433,503 B2	9/2016	Tsukashima et al.
8,951,286 B2	2/2015	Sugimoto et al.	9,445,898 B2	9/2016	Tuval et al.
8,956,406 B2	2/2015	Subramanian et al.	9,452,048 B2	9/2016	O'Beirne et al.
8,956,407 B2	2/2015	Macoviak et al.	9,474,605 B2	10/2016	Rowe et al.
8,961,597 B2	2/2015	Subramanian et al.	9,474,606 B2	10/2016	Zipory et al.
8,968,335 B2	3/2015	Robinson et al.	9,474,608 B2	10/2016	Mathis et al.
8,968,393 B2	3/2015	Rothstein	9,492,276 B2	11/2016	Lee et al.
8,974,445 B2	3/2015	Warnking et al.	9,498,228 B2	11/2016	Dale et al.
8,974,525 B2	3/2015	Nieminen et al.	9,498,330 B2	11/2016	Solem
8,979,923 B2	3/2015	Spence et al.	9,498,331 B2	11/2016	Chang et al.
8,979,925 B2	3/2015	Chang et al.	9,504,570 B2	11/2016	Hauser et al.
8,992,605 B2	3/2015	Zakai et al.	9,510,829 B2	12/2016	Goldfarb et al.
8,998,794 B2	4/2015	Mortier et al.	9,510,837 B2	12/2016	Seguin
8,998,933 B2	4/2015	Rothstein et al.	9,510,946 B2	12/2016	Chau et al.
9,011,463 B2	4/2015	Adams et al.	9,510,948 B2	12/2016	Padala et al.
9,011,468 B2	4/2015	Ketai et al.	9,526,613 B2	12/2016	Gross et al.
9,011,520 B2	4/2015	Miller et al.	9,526,614 B2	12/2016	Keränen
9,011,530 B2	4/2015	Reich et al.	9,526,616 B2	12/2016	Nieminen et al.
9,011,531 B2	4/2015	Rourke et al.	9,532,874 B2	1/2017	Griffin et al.
9,044,221 B2	6/2015	Zentgraf et al.	9,545,305 B2	1/2017	Wilson et al.
9,044,246 B2	6/2015	Goldfarb et al.	9,561,104 B2	2/2017	Miller et al.
9,050,187 B2	6/2015	Sugimoto et al.	9,561,105 B2	2/2017	Rowe
9,060,858 B2	6/2015	Thornton et al.	9,572,666 B2	2/2017	Basude et al.
9,066,710 B2	6/2015	Dale et al.	9,572,667 B2	2/2017	Solem
9,107,658 B2	8/2015	Schaller et al.	9,579,200 B2	2/2017	Lederman et al.
9,107,750 B2	8/2015	Cartledge et al.	9,592,118 B2	3/2017	Khairkhahan et al.
9,119,718 B2	9/2015	Keränen	9,592,122 B2	3/2017	Zipory et al.
9,119,719 B2	9/2015	Zipory et al.	9,597,184 B2	3/2017	Machold et al.
9,125,632 B2	9/2015	Loulmet et al.	9,610,082 B2	4/2017	Morris et al.
9,125,653 B2	9/2015	Kovach	9,610,161 B2	4/2017	Macoviak et al.
9,131,928 B2	9/2015	Zlotnick et al.	9,610,162 B2	4/2017	Zipory et al.
9,131,939 B1	9/2015	Call et al.	9,610,163 B2	4/2017	Khairkhahan et al.
9,168,137 B2	10/2015	Subramanian et al.	9,615,926 B2	4/2017	Lashinski et al.
9,173,646 B2	11/2015	Fabro	9,616,197 B2	4/2017	Serina et al.
9,179,896 B2	11/2015	Machold et al.	9,622,862 B2	4/2017	Lashinski et al.
9,180,005 B1	11/2015	Lashinski et al.	9,636,106 B2	5/2017	Meier et al.
9,180,006 B2	11/2015	Keranen	9,636,107 B2	5/2017	Morales et al.
9,180,007 B2	11/2015	Reich et al.	9,636,223 B2	5/2017	Khalil et al.
9,180,008 B2	11/2015	Yellin et al.	9,636,224 B2	5/2017	Zipory et al.
9,192,374 B2	11/2015	Zentgraf	9,642,706 B2	5/2017	Eidenschink
9,192,471 B2	11/2015	Bolling	9,649,106 B2	5/2017	Nobles et al.
9,192,472 B2	11/2015	Gross et al.	9,662,205 B2	5/2017	Eidenschink
			9,662,208 B2	5/2017	Padala et al.
			9,662,209 B2	5/2017	Gross et al.
			9,706,996 B2	7/2017	Nguyen et al.
			2001/0005787 A1	6/2001	Oz et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2002/0183837	A1	12/2002	Streeter et al.
2003/0105519	A1	6/2003	Fasol et al.
2003/0120340	A1	6/2003	Liska et al.
2003/0120341	A1	6/2003	Shennib et al.
2004/0019378	A1	1/2004	Hlavka et al.
2004/0024414	A1	2/2004	Downing
2004/0030382	A1	2/2004	St. Goar et al.
2004/0039442	A1	2/2004	St. Goar et al.
2004/0044350	A1	3/2004	Martin et al.
2004/0102839	A1	5/2004	Cohn et al.
2004/0127982	A1	7/2004	Machold et al.
2004/0127983	A1	7/2004	Mortier et al.
2004/0133063	A1	7/2004	McCarthy et al.
2004/0133240	A1	7/2004	Adams et al.
2004/0152947	A1	8/2004	Schroeder et al.
2004/0153144	A1	8/2004	Seguin et al.
2004/0158321	A1	8/2004	Reuter et al.
2004/0162610	A1	8/2004	Liska et al.
2004/0167539	A1	8/2004	Kuehen et al.
2004/0210240	A1	10/2004	Saint
2004/0220654	A1	11/2004	Mathis et al.
2004/0220657	A1	11/2004	Nieminen et al.
2004/0243227	A1	12/2004	Starksen et al.
2004/0254600	A1	12/2004	Zarbatany et al.
2004/0260394	A1	12/2004	Douk et al.
2004/0267083	A1	12/2004	McCarthy et al.
2005/0027351	A1	2/2005	Rueter et al.
2005/0033446	A1	2/2005	Deem et al.
2005/0049679	A1	3/2005	Taylor et al.
2005/0070999	A1	3/2005	Spence
2005/0071000	A1	3/2005	Liddicoat et al.
2005/0075723	A1	4/2005	Schroeder et al.
2005/0107810	A1	5/2005	Morales et al.
2005/0107811	A1	5/2005	Starksen et al.
2005/0107871	A1	5/2005	Realyvasquez et al.
2005/0137449	A1	6/2005	Nieminen et al.
2005/0137450	A1	6/2005	Aronson et al.
2005/0143811	A1	6/2005	Realyvasquez
2005/0148815	A1	7/2005	Mortier et al.
2005/0149014	A1	7/2005	Hauck et al.
2005/0159810	A1	7/2005	Filsoufi
2005/0177228	A1	8/2005	Solem et al.
2005/0184122	A1	8/2005	Hlavka et al.
2005/0197692	A1	9/2005	Pai et al.
2005/0197693	A1	9/2005	Pai et al.
2005/0197694	A1	9/2005	Pai et al.
2005/0209690	A1	9/2005	Mathis et al.
2005/0216039	A1	9/2005	Lederman
2005/0216078	A1	9/2005	Starksen et al.
2005/0222488	A1	10/2005	Chang et al.
2005/0222489	A1	10/2005	Rahdert et al.
2005/0228422	A1	10/2005	Machold et al.
2005/0240202	A1	10/2005	Shennib et al.
2005/0267529	A1	12/2005	Crockett et al.
2005/0267574	A1	12/2005	Cohn et al.
2005/0273138	A1	12/2005	To et al.
2005/0288777	A1	12/2005	Rhee et al.
2005/0288778	A1	12/2005	Shaoulian et al.
2006/0015178	A1	1/2006	Moaddeb et al.
2006/0025787	A1	2/2006	Morales et al.
2006/0069429	A1	3/2006	Spence et al.
2006/0100699	A1	5/2006	Vidlund et al.
2006/0106278	A1	5/2006	Machold et al.
2006/0106279	A1	5/2006	Machold et al.
2006/0122633	A1	6/2006	To et al.
2006/0136053	A1	6/2006	Rourke et al.
2006/0149368	A1	7/2006	Spence
2006/0161040	A1	7/2006	McCarthy et al.
2006/0161169	A1	7/2006	Nieminen et al.
2006/0167474	A1	7/2006	Bloom et al.
2006/0178700	A1	8/2006	Quinn
2006/0184230	A1	8/2006	Solem et al.
2006/0184242	A1	8/2006	Lichtenstein
2006/0195012	A1	8/2006	Mortier et al.
2006/0206203	A1	9/2006	Yang et al.
2006/0229708	A1	10/2006	Powell et al.
2006/0241745	A1	10/2006	Solem
2006/0241746	A1	10/2006	Shaoulian et al.
2006/0252984	A1	11/2006	Rahdert et al.
2006/0271174	A1	11/2006	Nieminen et al.
2006/0281968	A1	12/2006	Duran et al.
2006/0282161	A1	12/2006	Huynh et al.
2006/0293698	A1	12/2006	Douk
2007/0027533	A1	2/2007	Douk
2007/0038293	A1	2/2007	St. Goar et al.
2007/0038297	A1	2/2007	Bobo et al.
2007/0050022	A1	3/2007	Vidlund et al.
2007/0055206	A1	3/2007	To et al.
2007/0055368	A1	3/2007	Rhee et al.
2007/0061010	A1	3/2007	Hauser et al.
2007/0066863	A1	3/2007	Rafiee et al.
2007/0067027	A1	3/2007	Moaddeb et al.
2007/0073391	A1	3/2007	Bourang et al.
2007/0078297	A1	4/2007	Rafiee et al.
2007/0080188	A1	4/2007	Spence et al.
2007/0100356	A1	5/2007	Lucatero et al.
2007/0100439	A1	5/2007	Cangialosi et al.
2007/0112244	A1	5/2007	McCarthy et al.
2007/0112424	A1	5/2007	Spence et al.
2007/0118151	A1	5/2007	Davidson
2007/0118215	A1	5/2007	Moaddeb
2007/0129737	A1	6/2007	Goldfarb et al.
2007/0135913	A1	6/2007	Moaddeb et al.
2007/0156235	A1	7/2007	Rourke et al.
2007/0173926	A1	7/2007	Bobo et al.
2007/0185571	A1	8/2007	Kapadia et al.
2007/0198038	A1	8/2007	Cohen et al.
2007/0203391	A1	8/2007	Bloom et al.
2007/0213758	A1	9/2007	Rourke et al.
2007/0232941	A1	10/2007	Rabinovich
2007/0233238	A1	10/2007	Huynh et al.
2007/0244554	A1	10/2007	Rafiee et al.
2007/0244555	A1	10/2007	Rafiee et al.
2007/0244556	A1	10/2007	Rafiee et al.
2007/0255396	A1	11/2007	Douk et al.
2007/0265658	A1	11/2007	Nelson et al.
2007/0265702	A1	11/2007	Lattouf
2007/0270793	A1	11/2007	Lattouf
2007/0276437	A1	11/2007	Call et al.
2007/0276478	A1	11/2007	Marmureanu et al.
2007/0282429	A1	12/2007	Hauser et al.
2007/0293943	A1	12/2007	Quinn
2008/0004597	A1	1/2008	Lattouf et al.
2008/0015688	A1	1/2008	Hill et al.
2008/0039935	A1	2/2008	Buch et al.
2008/0050347	A1	2/2008	Ichim
2008/0065205	A1	3/2008	Nguyen et al.
2008/0091059	A1	4/2008	Machold et al.
2008/0091264	A1	4/2008	Machold et al.
2008/0140188	A1	6/2008	Rahdert et al.
2008/0140190	A1	6/2008	Macoviak et al.
2008/0167714	A1	7/2008	St. Goar et al.
2008/0177380	A1	7/2008	Starksen et al.
2008/0183283	A1	7/2008	Downing
2008/0183285	A1	7/2008	Shaoulian et al.
2008/0195126	A1	8/2008	Solem
2008/0195200	A1	8/2008	Vidlund et al.
2008/0200981	A1	8/2008	Shaoulian et al.
2008/0228032	A1	9/2008	Starksen et al.
2008/0228201	A1	9/2008	Zarbatany et al.
2008/0228265	A1	9/2008	Spence et al.
2008/0228266	A1	9/2008	McNamara et al.
2008/0228272	A1	9/2008	Moaddeb et al.
2008/0234701	A1	9/2008	Morales et al.
2008/0234702	A1	9/2008	Morales et al.
2008/0234813	A1	9/2008	Heuser
2008/0243150	A1	10/2008	Starksen et al.
2008/0249504	A1	10/2008	Lattouf et al.
2008/0249618	A1	10/2008	Huynh et al.
2008/0319541	A1	12/2008	Filsoufi
2009/0043381	A1	2/2009	Macoviak et al.
2009/0069885	A1	3/2009	Rahdert et al.
2009/0076600	A1	3/2009	Quinn
2009/0088838	A1	4/2009	Shaolian et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0118744 A1	5/2009	Wells et al.	2012/0185040 A1	7/2012	Rahdert et al.	
2009/0118825 A1	5/2009	Rourke et al.	2012/0197388 A1*	8/2012	Khairkhahan .....	A61B 17/0401 623/2.11
2009/0149949 A1	6/2009	Quinn	2012/0203072 A1	8/2012	Lattouf et al.	
2009/0177266 A1	7/2009	Powell et al.	2012/0209376 A1	8/2012	Hauser et al.	
2009/0182418 A1	7/2009	Solem et al.	2012/0209379 A1	8/2012	Shaolian et al.	
2009/0182419 A1	7/2009	Bolling	2012/0215305 A1	8/2012	Le et al.	
2009/0209950 A1	8/2009	Starksen	2012/0221101 A1	8/2012	Moaddeb et al.	
2009/0216322 A1	8/2009	Le et al.	2012/0271331 A1	10/2012	To et al.	
2009/0222081 A1	9/2009	Linder et al.	2012/0310331 A1	12/2012	Eigler et al.	
2009/0228100 A1	9/2009	Solem et al.	2012/0323314 A1	12/2012	Callas et al.	
2009/0287179 A1	11/2009	Machold et al.	2013/0023985 A1*	1/2013	Khairkhahan .....	A61L 27/042 623/2.38
2009/0306622 A1	12/2009	Machold et al.	2013/0035757 A1	2/2013	Zentgraf et al.	
2009/0306685 A1	12/2009	Fill	2013/0110230 A1	5/2013	Solem	
2009/0326648 A1	12/2009	Machold et al.	2013/0116776 A1	5/2013	Gross et al.	
2010/0023056 A1	1/2010	Johansson et al.	2013/0123913 A1	5/2013	Kuehn	
2010/0023118 A1	1/2010	Medlock et al.	2013/0131791 A1	5/2013	Hlavka et al.	
2010/0030330 A1	2/2010	Bobo et al.	2013/0253639 A1	9/2013	Alkhatib	
2010/0036483 A1	2/2010	Rourke et al.	2013/0253641 A1	9/2013	Lattouf	
2010/0049213 A1	2/2010	Serina et al.	2013/0282059 A1	10/2013	Ketai et al.	
2010/0094248 A1	4/2010	Nguyen et al.	2013/0304093 A1	11/2013	Serina et al.	
2010/0121349 A1	5/2010	Meier et al.	2013/0304197 A1	11/2013	Buchbinder et al.	
2010/0121433 A1	5/2010	Bolling et al.	2014/0039607 A1	2/2014	Kovach	
2010/0121435 A1	5/2010	Subramanian et al.	2014/0066693 A1	3/2014	Goldfarb et al.	
2010/0121437 A1	5/2010	Subramanian et al.	2014/0067048 A1	3/2014	Chau et al.	
2010/0131057 A1	5/2010	Subramanian et al.	2014/0088693 A1	3/2014	Seguin et al.	
2010/0137887 A1	6/2010	Crockett et al.	2014/0135799 A1	5/2014	Henderson	
2010/0152845 A1	6/2010	Bloom et al.	2014/0148849 A1	5/2014	Serina et al.	
2010/0161044 A1	6/2010	Chang et al.	2014/0155783 A1	6/2014	Starksen et al.	
2010/0185172 A1	7/2010	Fabro	2014/0172084 A1	6/2014	Callas et al.	
2010/0185273 A1	7/2010	Solem et al.	2014/0188108 A1	7/2014	Goodine et al.	
2010/0198056 A1	8/2010	Fabro et al.	2014/0207154 A1	7/2014	Bielefeld et al.	
2010/0198192 A1	8/2010	Serina et al.	2014/0207161 A1	7/2014	Dell et al.	
2010/0198208 A1	8/2010	Napp et al.	2014/0222138 A1	8/2014	Machold et al.	
2010/0210899 A1	8/2010	Schankereli	2014/0228871 A1	8/2014	Cohen et al.	
2010/0217283 A1	8/2010	St. Goar et al.	2014/0243860 A1	8/2014	Morris et al.	
2010/0249920 A1	9/2010	Bolling et al.	2014/0243894 A1	8/2014	Groothuis et al.	
2010/0280602 A1	11/2010	Mathis	2014/0243963 A1	8/2014	Sheps et al.	
2010/0298929 A1	11/2010	Thornton et al.	2014/0257341 A1	9/2014	Eidenschink et al.	
2010/0298930 A1	11/2010	Orlov	2014/0275757 A1	9/2014	Goodwin et al.	
2010/0318184 A1	12/2010	Spence	2014/0276648 A1	9/2014	Hammer et al.	
2010/0331971 A1	12/2010	Keränen et al.	2014/0276971 A1	9/2014	Kovach	
2011/0009957 A1	1/2011	Langberg et al.	2014/0276979 A1	9/2014	Sauer et al.	
2011/0011917 A1	1/2011	Loulmet	2014/0309661 A1	10/2014	Sheps et al.	
2011/0015722 A1	1/2011	Hauser et al.	2014/0336756 A1	11/2014	Lee et al.	
2011/0022164 A1	1/2011	Quinn et al.	2014/0364875 A1	12/2014	Zentgraf	
2011/0022166 A1	1/2011	Dahlgren et al.	2014/0371843 A1	12/2014	Wilson et al.	
2011/0060407 A1	3/2011	Ketai et al.	2014/0379002 A1	12/2014	Morris et al.	
2011/0066234 A1	3/2011	Gordon et al.	2014/0379006 A1	12/2014	Sutherland et al.	
2011/0092988 A1	4/2011	Cohen et al.	2015/0018940 A1	1/2015	Quill et al.	
2011/0093063 A1	4/2011	Schreck	2015/0018941 A1	1/2015	Lee et al.	
2011/0106106 A1	5/2011	Meier et al.	2015/0032127 A1	1/2015	Gammie et al.	
2011/0106117 A1	5/2011	Mathis et al.	2015/0038988 A1	2/2015	Tegels et al.	
2011/0144743 A1	6/2011	Lattouf	2015/0045815 A1	2/2015	Eidenschink	
2011/0172754 A1	7/2011	Starksen et al.	2015/0051697 A1	2/2015	Spence et al.	
2011/0207996 A1	8/2011	Starksen	2015/0057682 A1	2/2015	Kovach	
2011/0213387 A1	9/2011	Nguyen et al.	2015/0066138 A1	3/2015	Alexander et al.	
2011/0224784 A1	9/2011	Quinn	2015/0073547 A1	3/2015	Eliassen et al.	
2011/0230961 A1	9/2011	Langer et al.	2015/0105804 A1	4/2015	Dell et al.	
2011/0230962 A1	9/2011	Moaddeb et al.	2015/0105855 A1	4/2015	Cabiri et al.	
2011/0251684 A1	10/2011	Rahdert et al.	2015/0112432 A1	4/2015	Reich et al.	
2011/0257740 A1	10/2011	Shaoulian et al.	2015/0119981 A1	4/2015	Khairkhahan et al.	
2011/0257741 A1	10/2011	Moaddeb et al.	2015/0127091 A1	5/2015	Cecere et al.	
2011/0264208 A1	10/2011	Duffy et al.	2015/0133999 A1	5/2015	Robinson et al.	
2012/0010461 A1	1/2012	Goldfarb et al.	2015/0134050 A1	5/2015	Solem et al.	
2012/0041548 A1	2/2012	Crabtree	2015/0134053 A1	5/2015	Morris et al.	
2012/0053680 A1	3/2012	Bolling et al.	2015/0134055 A1	5/2015	Spence et al.	
2012/0065464 A1	3/2012	Ellis et al.	2015/0134057 A1	5/2015	Rourke et al.	
2012/0095552 A1	4/2012	Spence et al.	2015/0142105 A1	5/2015	Bolling et al.	
2012/0101442 A1	4/2012	Legaspi et al.	2015/0157459 A1	6/2015	Macoviak et al.	
2012/0109288 A1	5/2012	Bolling	2015/0164639 A1	6/2015	Starksen et al.	
2012/0109289 A1	5/2012	Bolling	2015/0173740 A1	6/2015	Sugimoto et al.	
2012/0123532 A1	5/2012	Mathis	2015/0173900 A1	6/2015	Hauser et al.	
2012/0136433 A1	5/2012	Marmureanu et al.	2015/0182223 A1	7/2015	Ketai et al.	
2012/0158020 A1	6/2012	Crockett et al.	2015/0223793 A1	8/2015	Goldfarb et al.	
2012/0179184 A1	7/2012	Orlov	2015/0272586 A1	10/2015	Herman et al.	
			2015/0272734 A1	10/2015	Sheps et al.	
			2015/0297212 A1	10/2015	Reich et al.	

(56)

**References Cited**

## U.S. PATENT DOCUMENTS

2015/0313713	A1	11/2015	Zentgraf et al.
2015/0335430	A1	11/2015	Loulmet et al.
2015/0366556	A1	12/2015	Khairkhahan et al.
2015/0366666	A1	12/2015	Khairkhahan et al.
2016/0008132	A1	1/2016	Cabiri et al.
2016/0015515	A1	1/2016	Lashinski et al.
2016/0015517	A1	1/2016	Sutherland et al.
2016/0022419	A1	1/2016	Yellin et al.
2016/0038285	A1	2/2016	Glenn et al.
2016/0038286	A1	2/2016	Yellin et al.
2016/0058557	A1	3/2016	Reich et al.
2016/0067043	A1	3/2016	Machold et al.
2016/0106420	A1	4/2016	Foerster et al.
2016/0113762	A1	4/2016	Clague et al.
2016/0113767	A1	4/2016	Miller et al.
2016/0120642	A1	5/2016	Shaolian et al.
2016/0143737	A1	5/2016	Zentgraf et al.
2016/0174979	A1	6/2016	Wei
2016/0192925	A1	7/2016	Bachman
2016/0242909	A1	8/2016	Ketai et al.
2016/0262887	A1	9/2016	Chang et al.
2016/0287387	A1	10/2016	Wei
2016/0354082	A1	12/2016	Oz et al.
2016/0374812	A1	12/2016	Machold et al.
2017/0007405	A1	1/2017	Griffin et al.
2017/0020521	A1	1/2017	Krone et al.
2017/0042546	A1	2/2017	Goldfarb et al.
2017/0049455	A1	2/2017	Seguin
2017/0055969	A1	3/2017	Machold et al.
2017/0143330	A1	5/2017	Basude et al.
2017/0189013	A1	7/2017	Morris et al.
2017/0202554	A1	7/2017	Eidenschink

\* cited by examiner

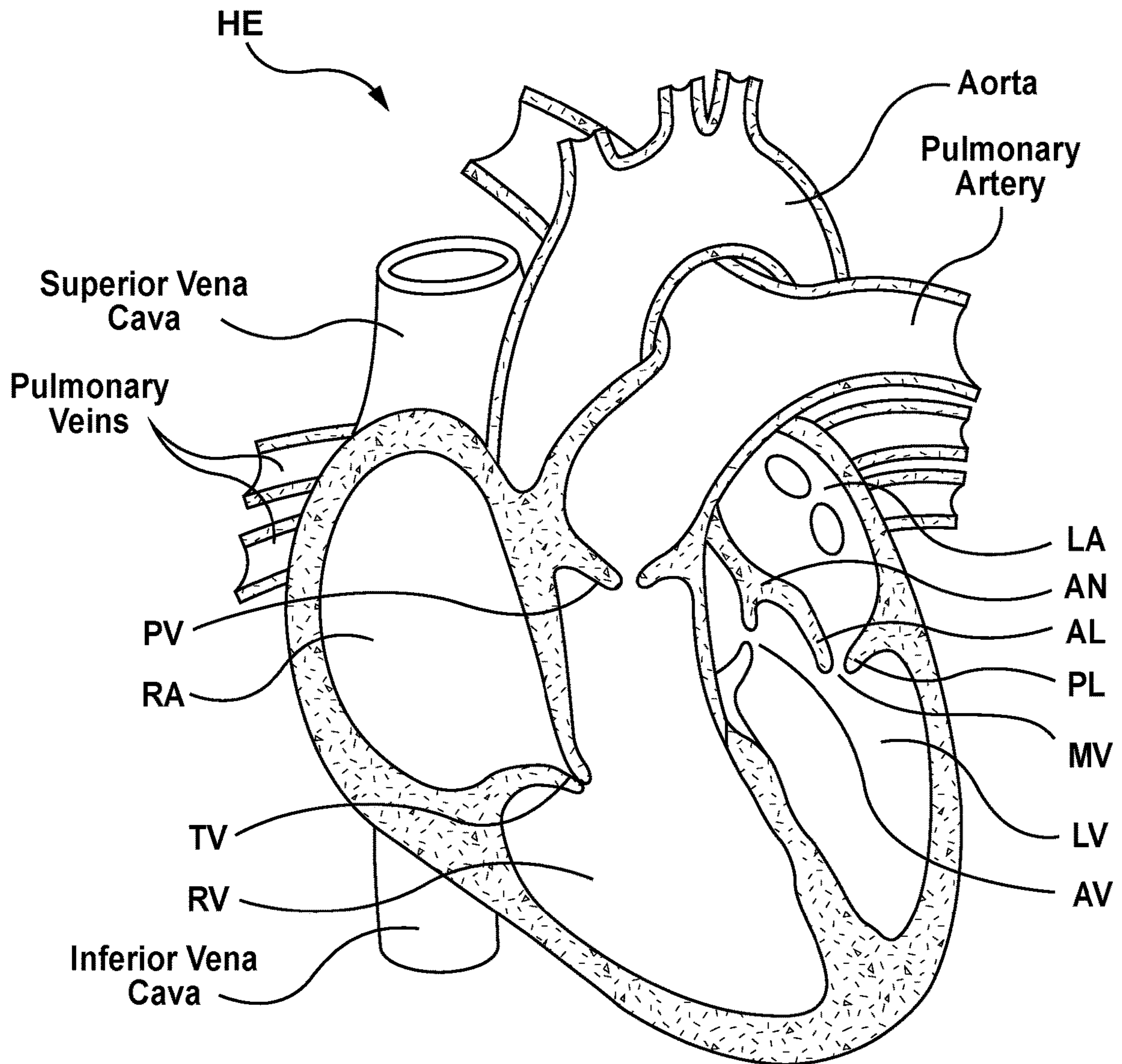


FIG. 1



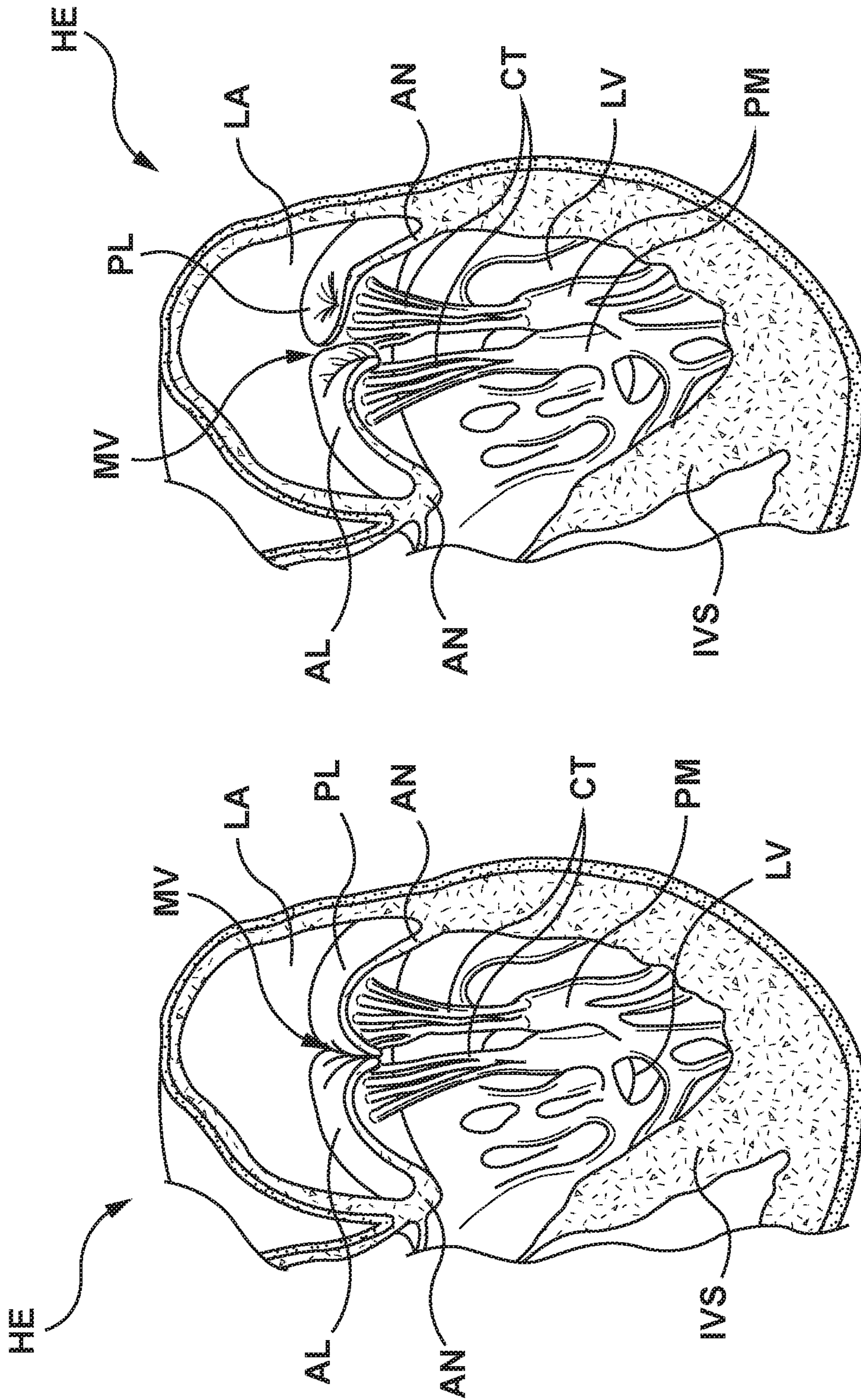
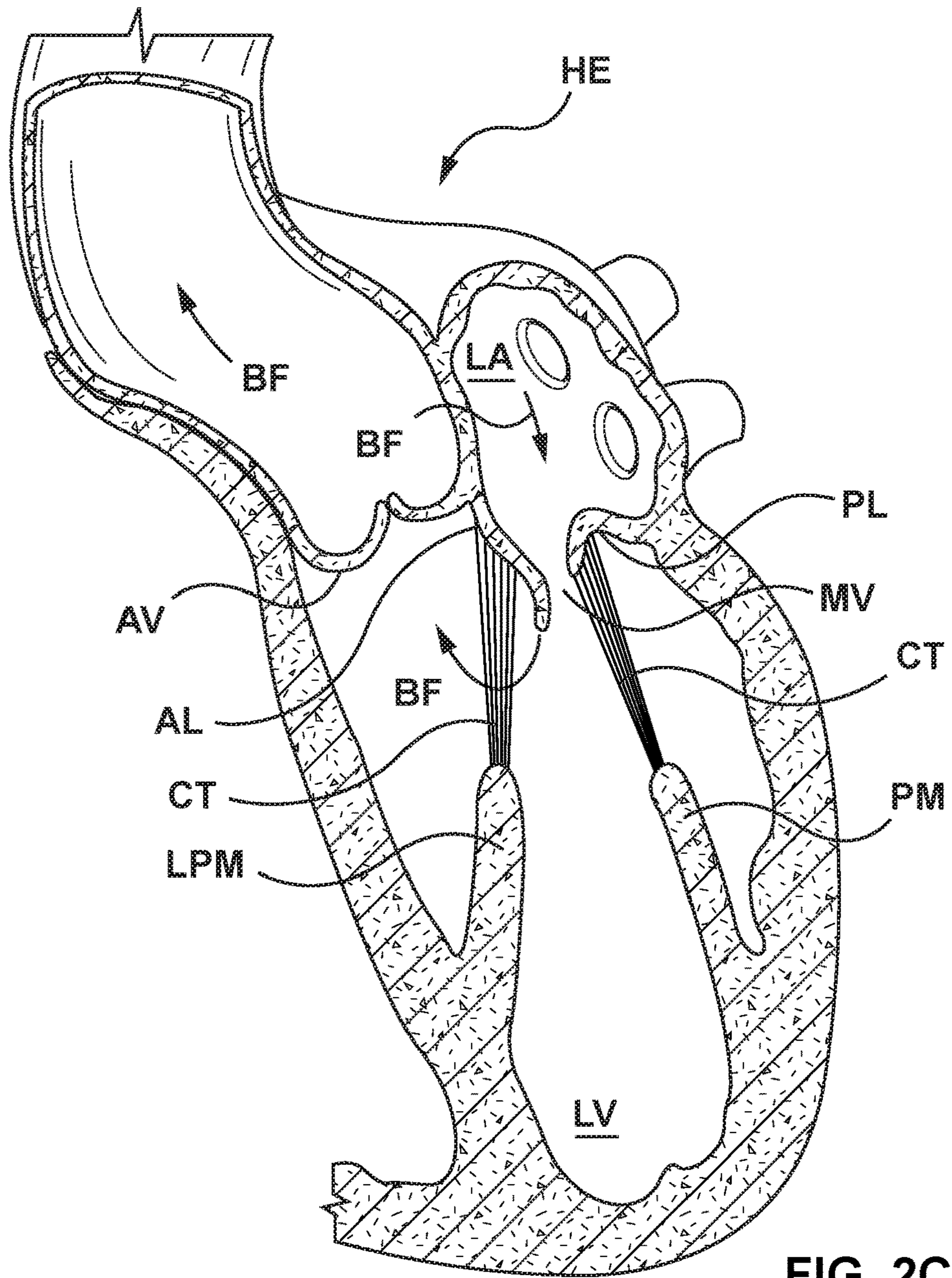
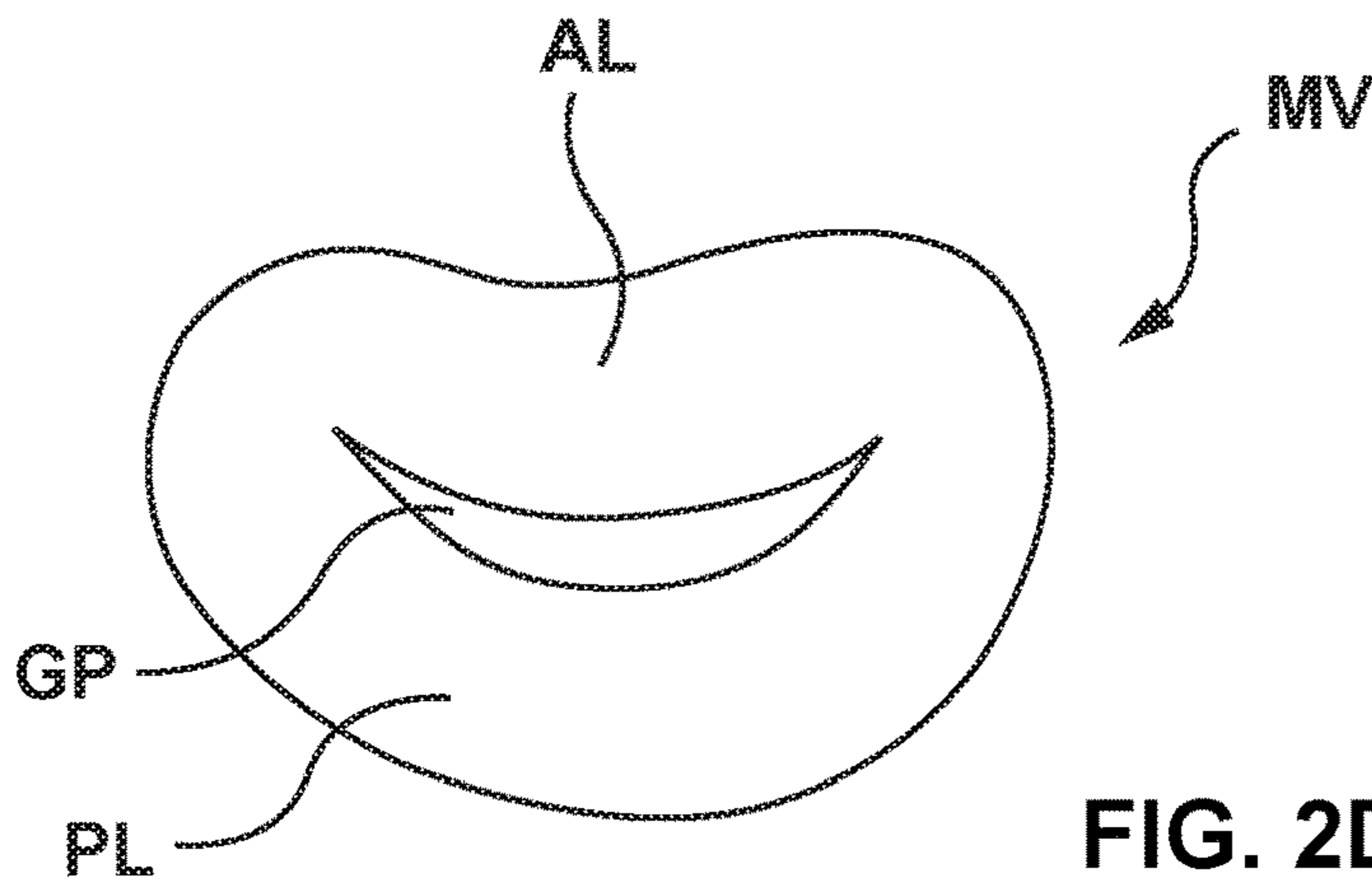


FIG. 2A

FIG. 2B



**FIG. 2C**



**FIG. 2D**

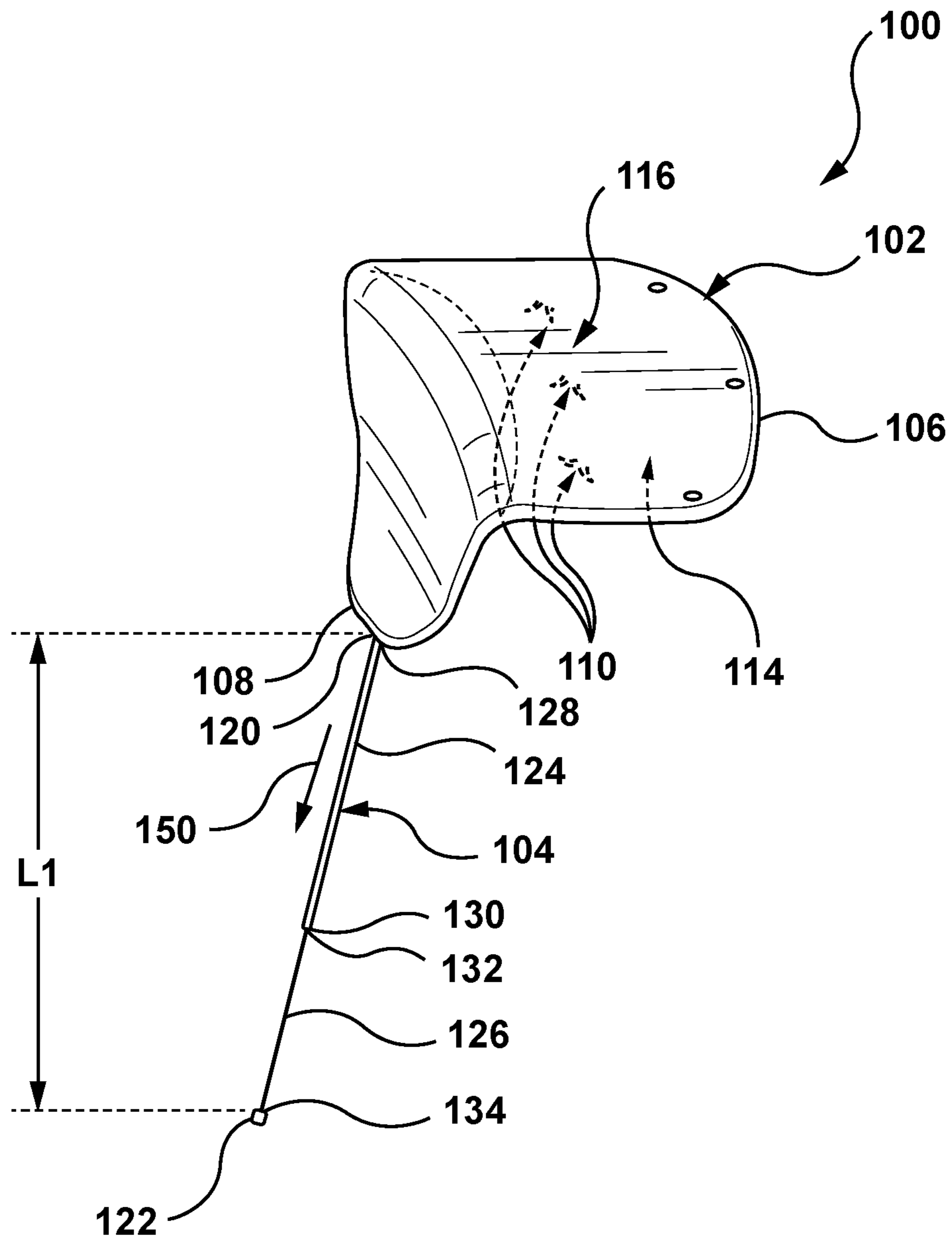


FIG. 3A

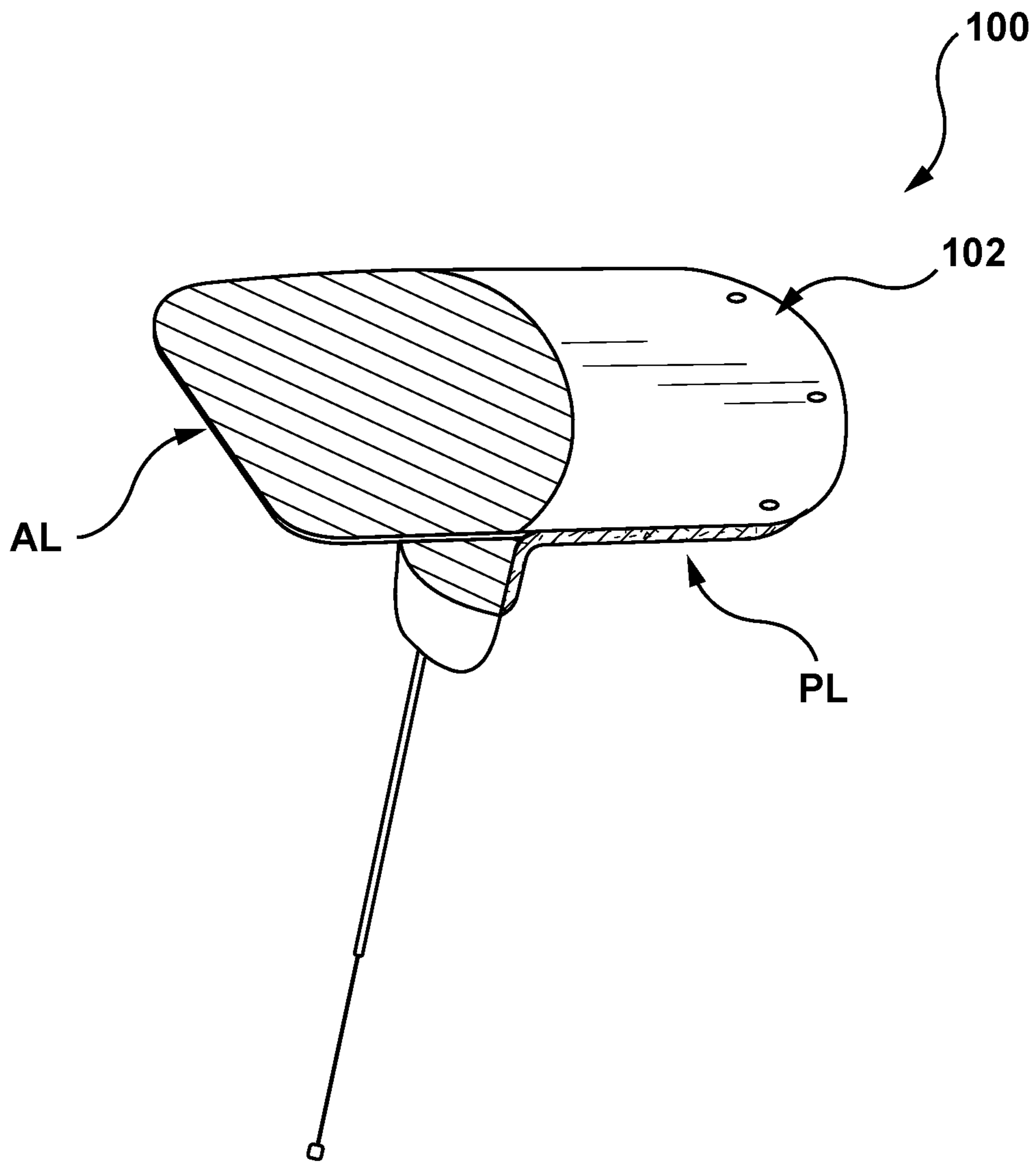
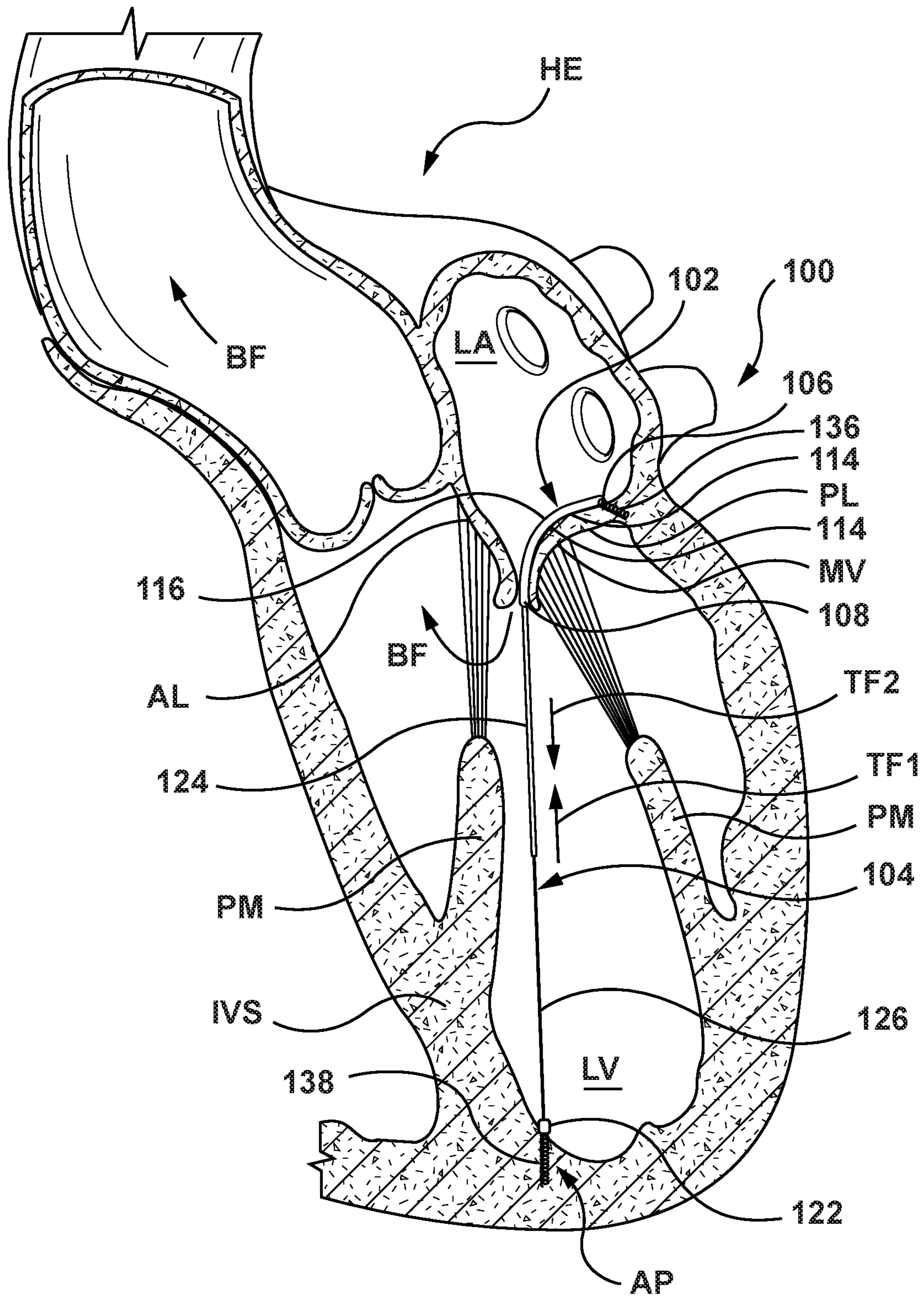
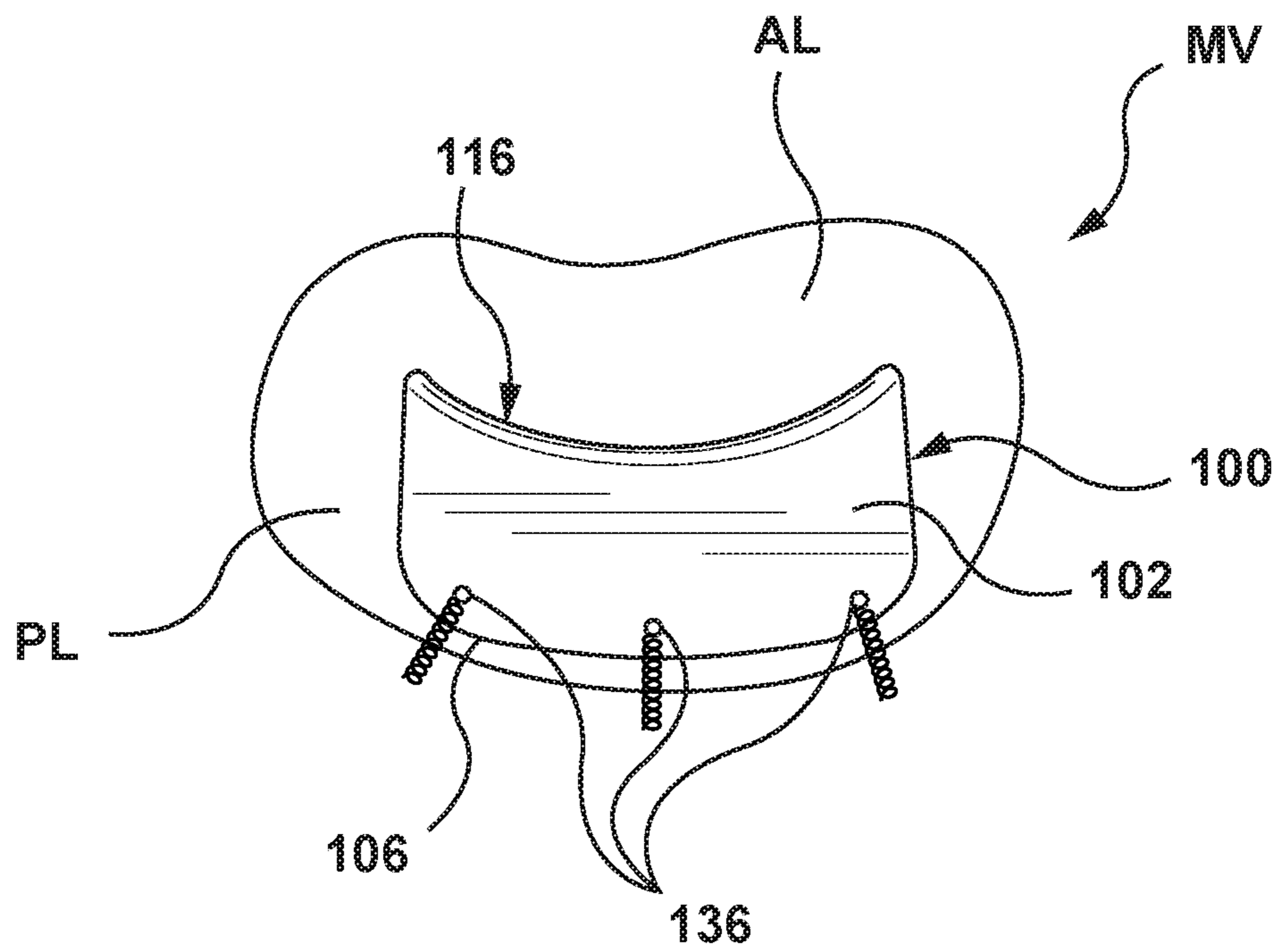


FIG. 3B





**FIG. 5**



**FIG. 6**

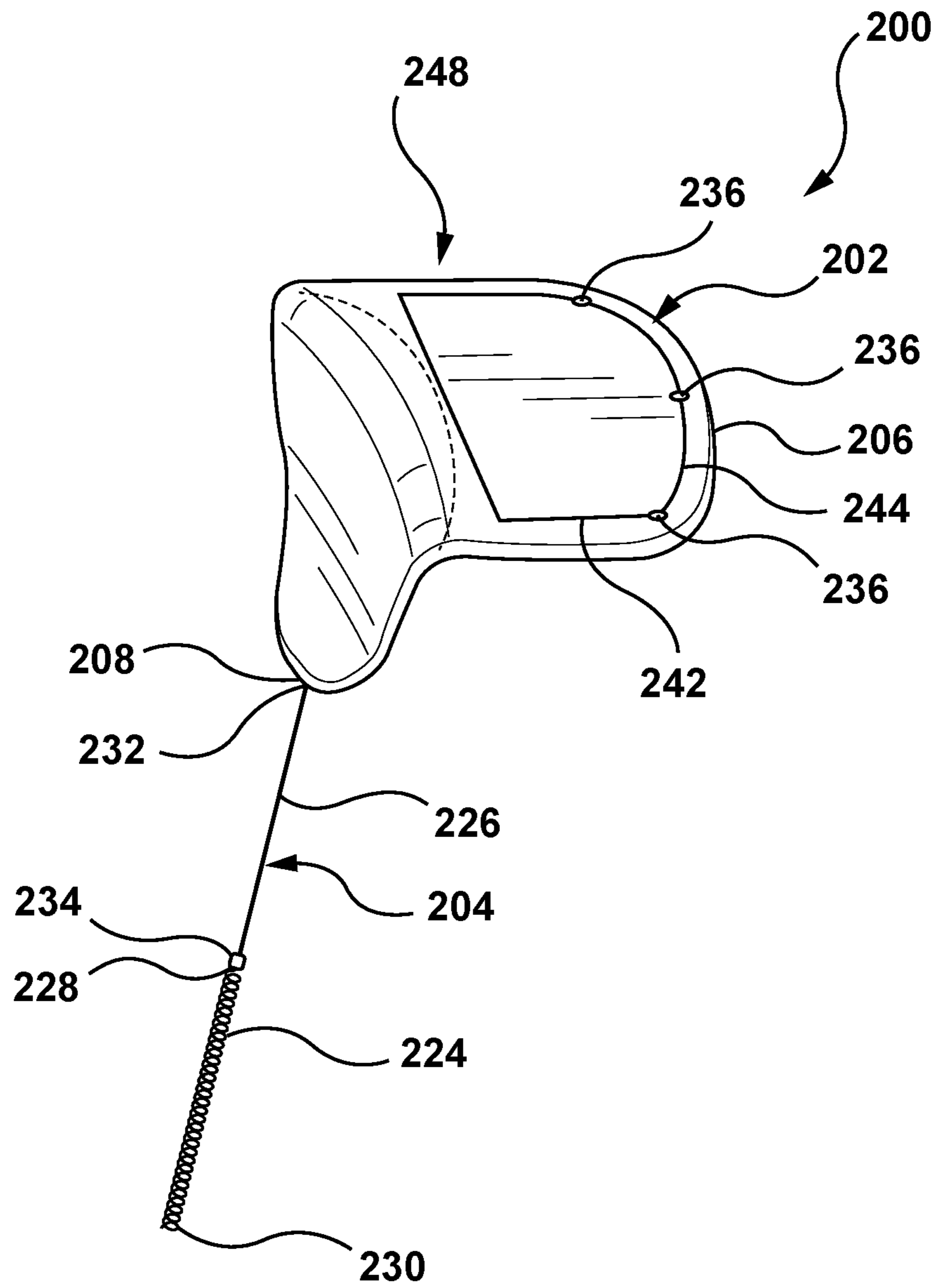


FIG. 7A



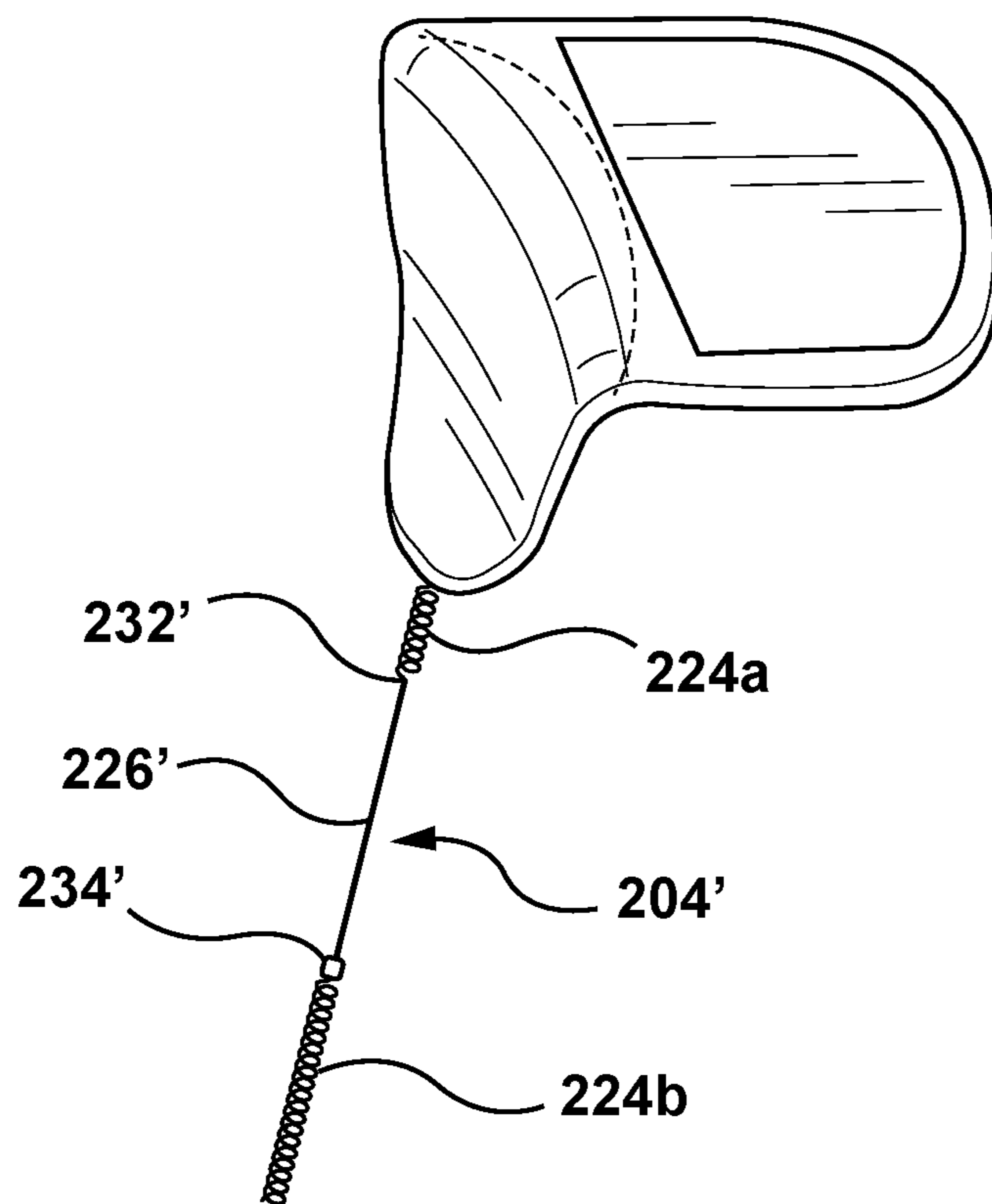
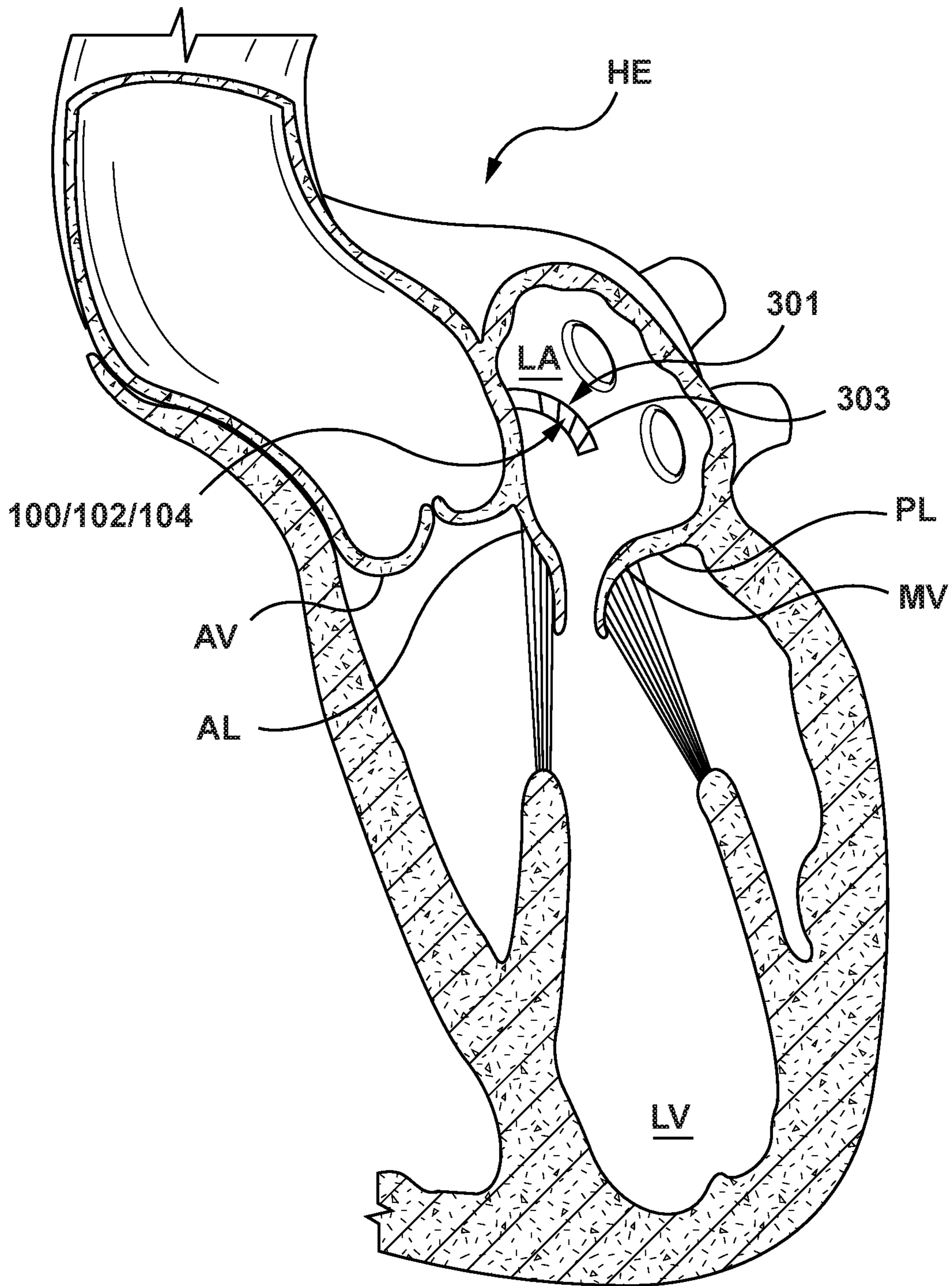
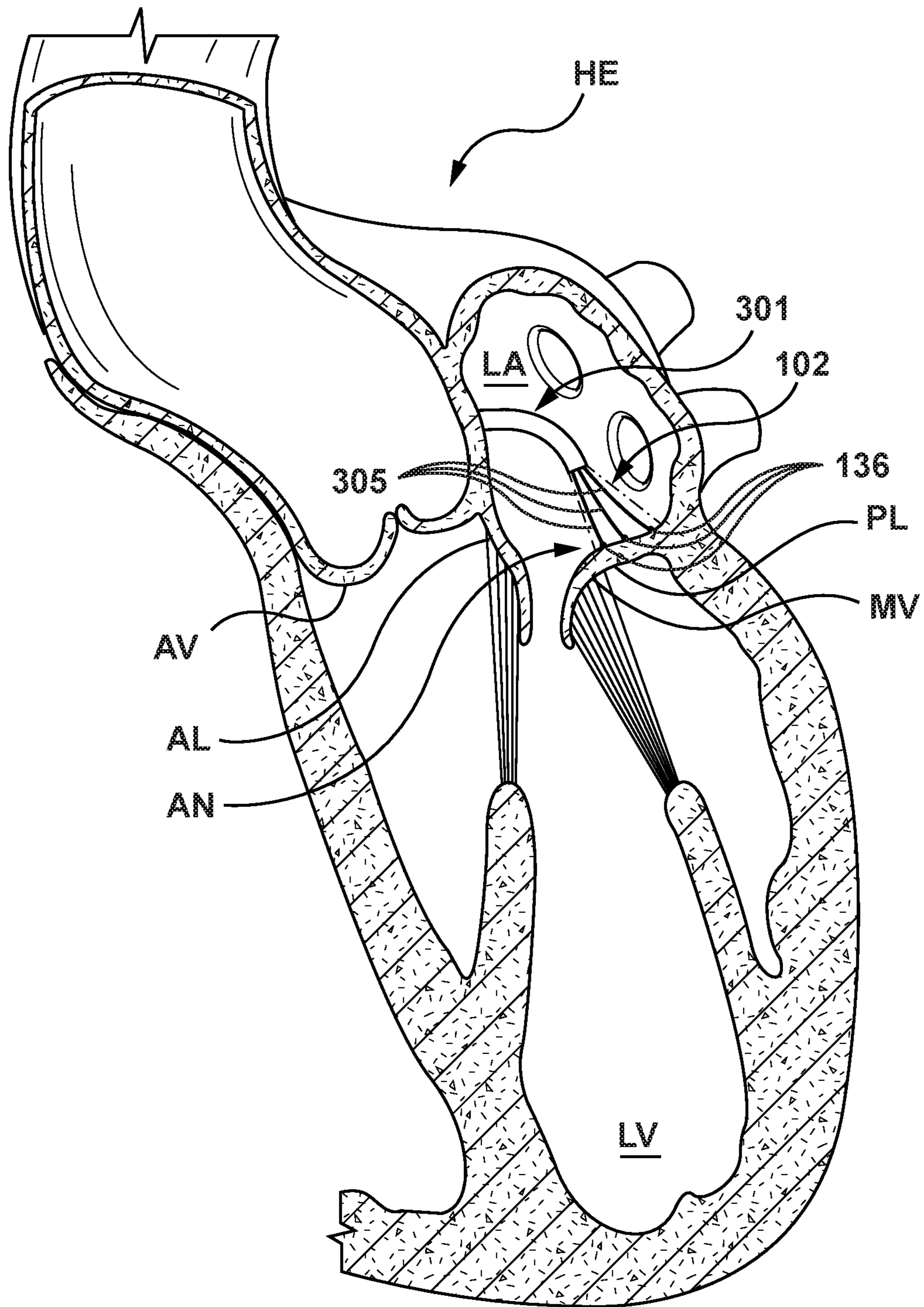


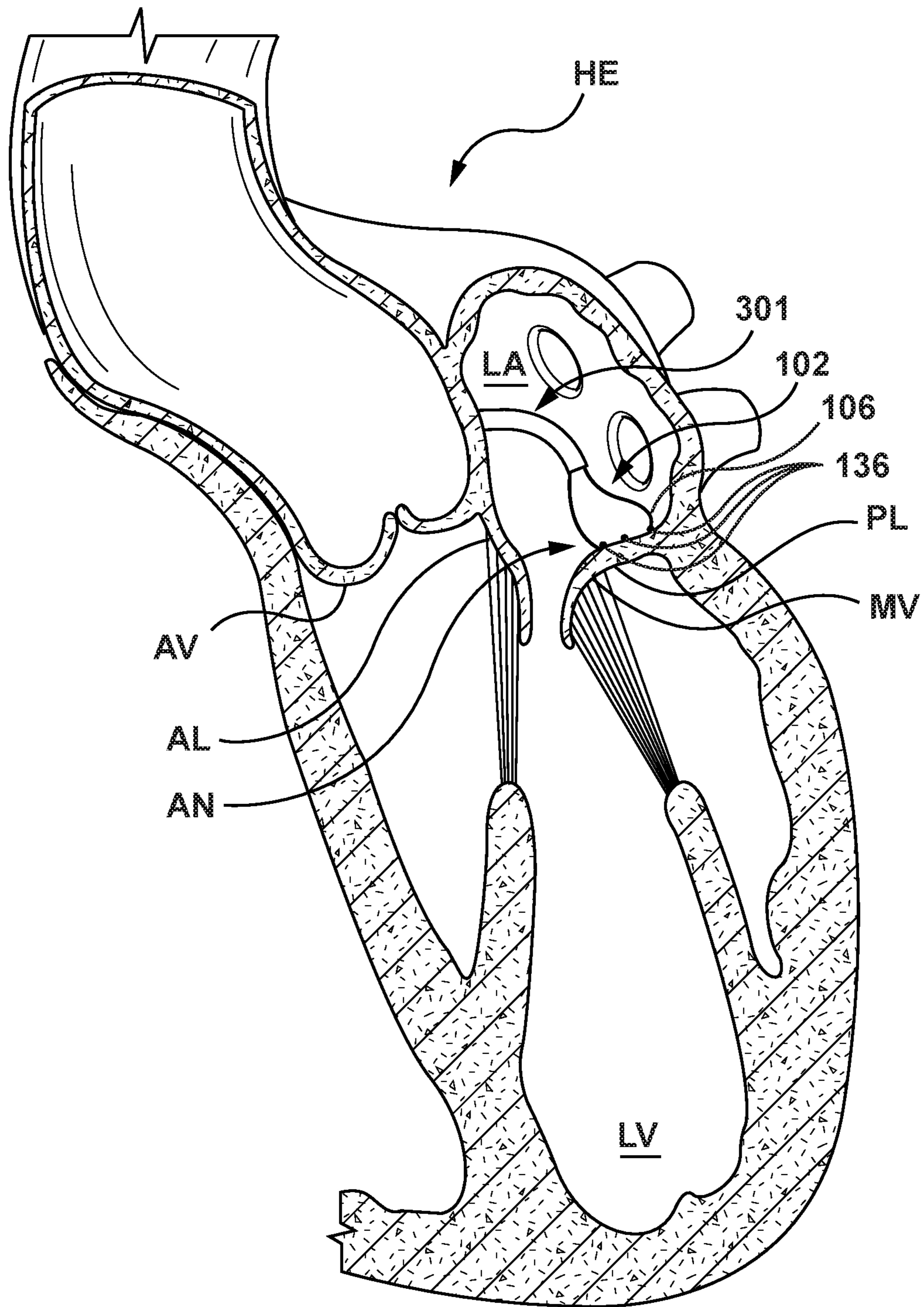
FIG. 7B



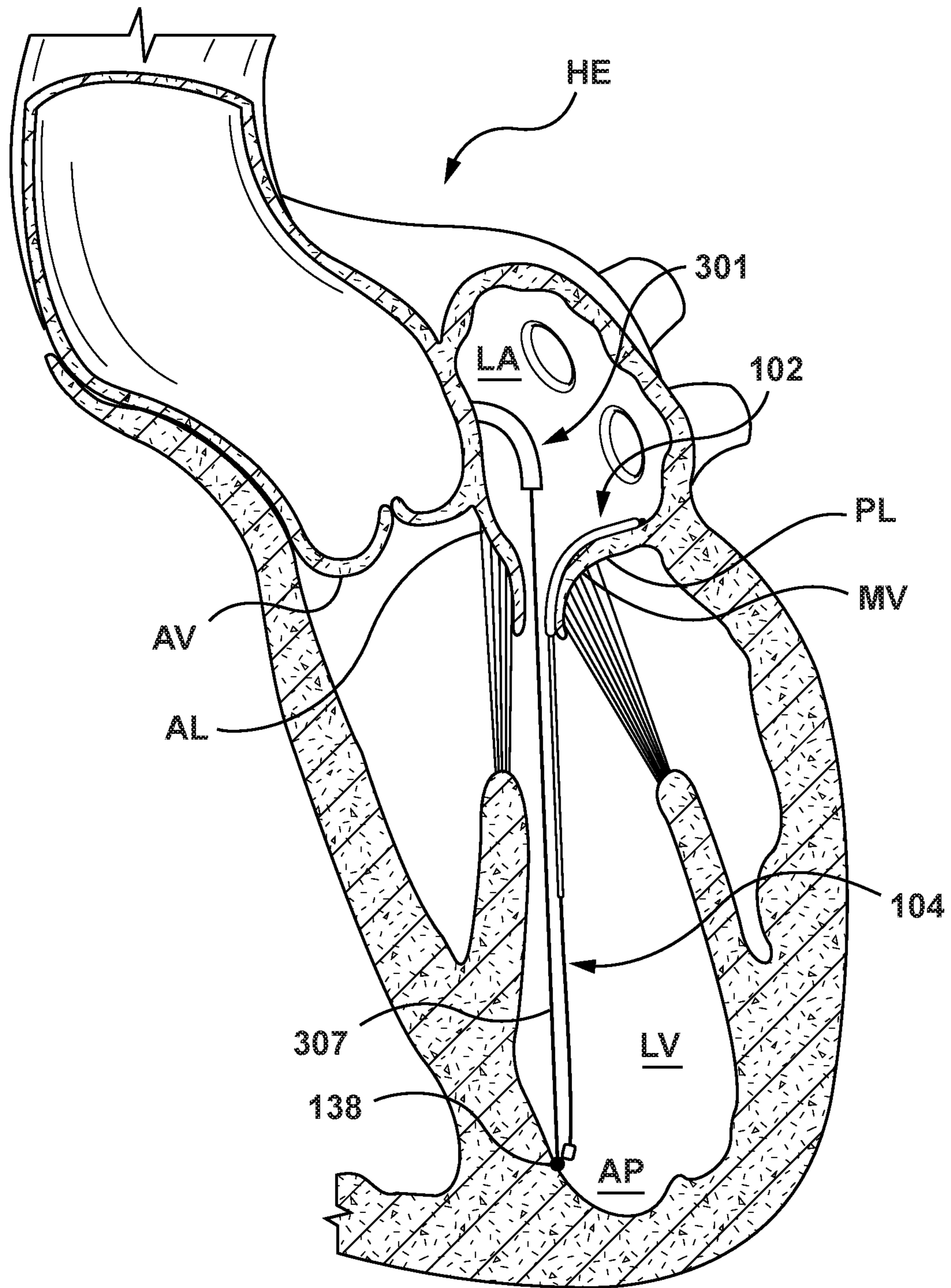
**FIG. 8**



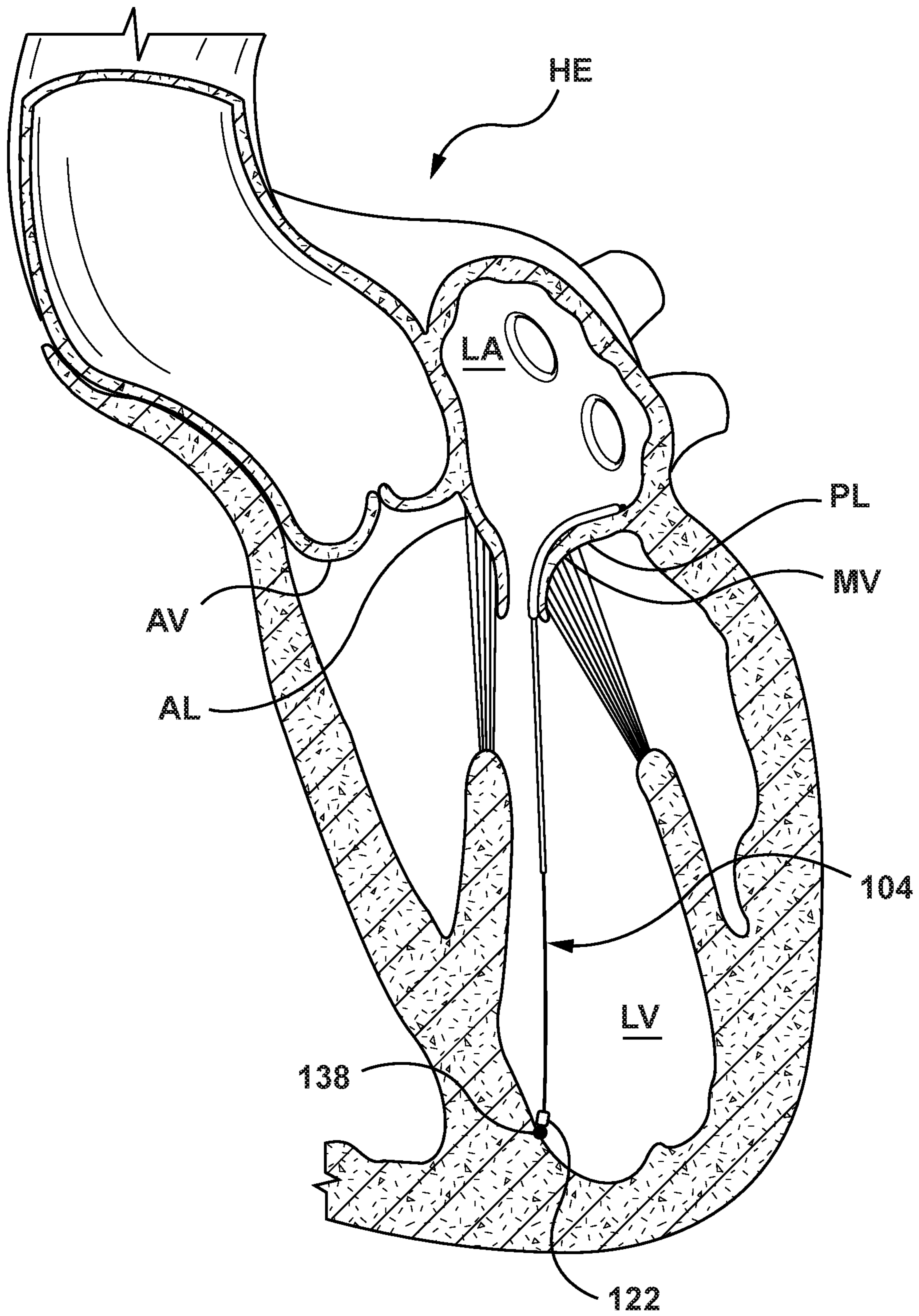
**FIG. 9**



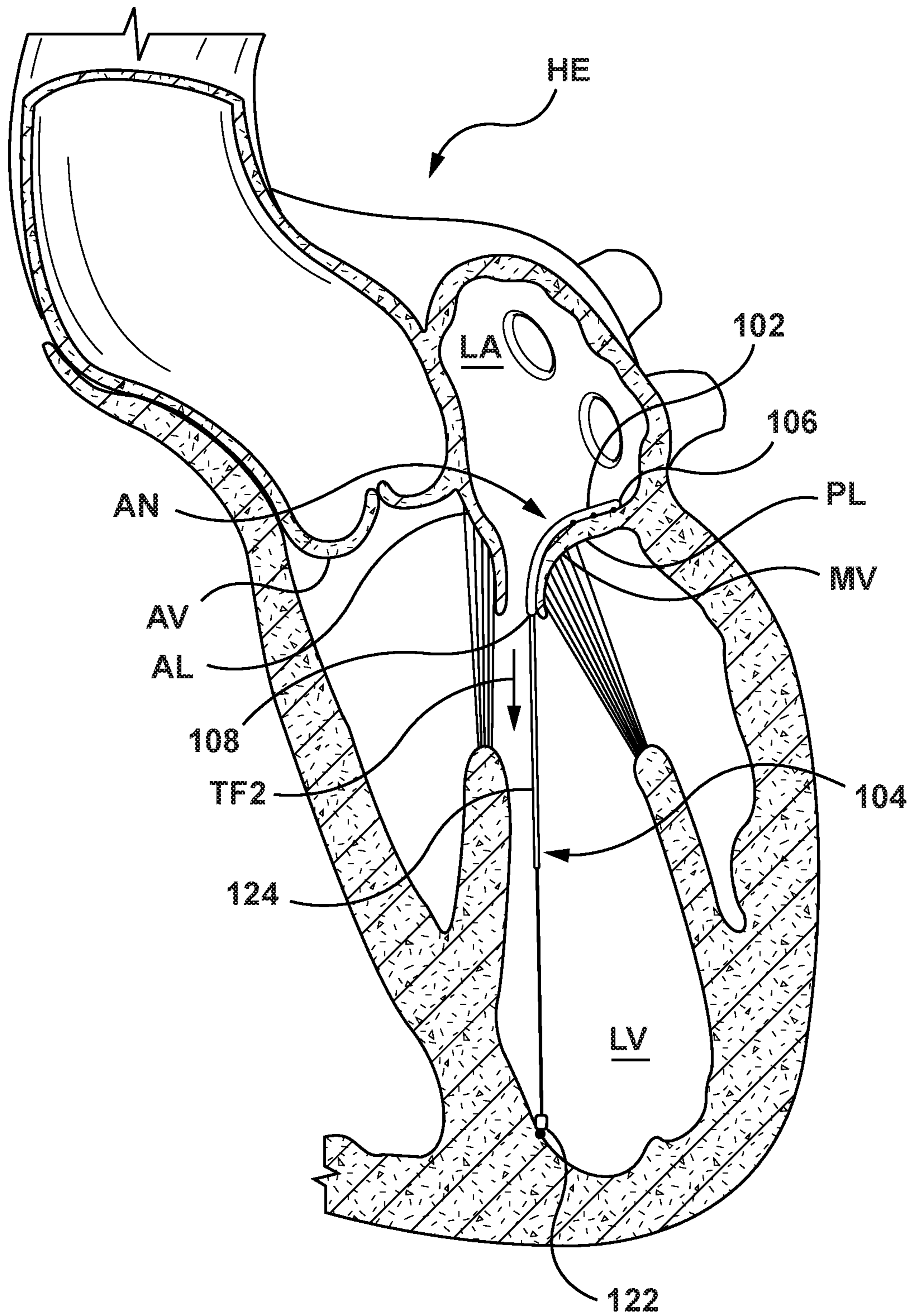
**FIG. 10**



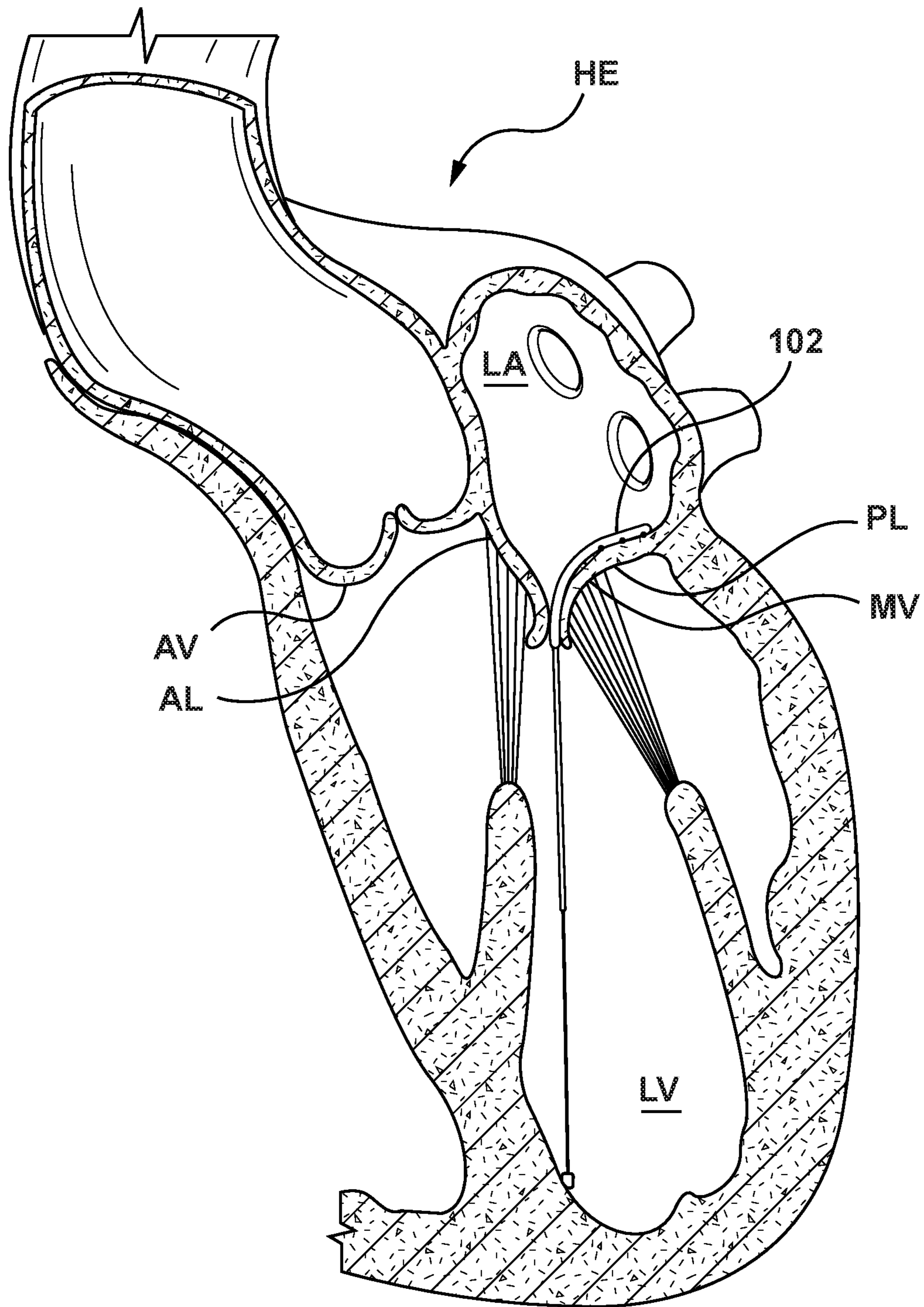
**FIG. 11**



**FIG. 12**



**FIG. 13**



**FIG. 14**



## FLEXIBLE CANOPY VALVE REPAIR SYSTEMS AND METHODS OF USE

### CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Ser. No. 62/645,306, filed Mar. 20, 2018, which is hereby incorporated by reference in its entirety for all purposes.

### FIELD OF THE INVENTION

The present technology relates generally to a system for repairing a valve suffering from regurgitation, and associated systems and methods.

### BACKGROUND OF THE INVENTION

The human heart is a four chambered, muscular organ that provides blood circulation through the body during a cardiac cycle. The four main chambers include the right atrium and right ventricle which supplies the pulmonary circulation, and the left atrium and left ventricle which supplies oxygenated blood received from the lungs to the remaining body. To ensure that blood flows in one direction through the heart, atrioventricular valves (tricuspid and mitral valves) are present between the junctions of the atrium and the ventricles, and semi-lunar valves (pulmonary valve and aortic valve) govern the exits of the ventricles leading to the lungs and the rest of the body. These valves contain leaflets or cusps that open and shut in response to blood pressure changes caused by the contraction and relaxation of the heart chambers. The leaflets move apart from each other to open and allow blood to flow downstream of the valve, and coapt to close and prevent backflow or regurgitation in an upstream manner.

The mitral valve, also known as the bicuspid or left atrioventricular valve, is a dual flap valve located between the left atrium and the left ventricle. The mitral valve serves to direct oxygenated blood from the lungs through the left side of the heart and into the aorta for distribution to the body. As with other valves of the heart, the mitral valve is a passive structure in that does not itself expend any energy and does not perform any active contractile function. The mitral valve includes two moveable leaflets, an anterior leaflet and a posterior leaflet, that each open and close in response to differential pressures on either side of the valve. Ideally, the leaflets move apart from each other when the valve is in an open configuration, and meet or “coapt” when the valve is in a closed configuration.

Diseases associated with heart valves, such as those caused by damage or a defect, can include stenosis and valvular insufficiency or regurgitation. These diseases can occur individually or concomitantly in the same valve. Valvular insufficiency or regurgitation occurs when the valve does not close completely, allowing blood to flow backwards, thereby causing the heart to be less efficient. A diseased or damaged valve, which can be congenital, age-related, drug-induced, or in some instances, caused by infection, can result in an enlarged, thickened heart that loses elasticity and efficiency. Some symptoms of heart valve diseases can include weakness, shortness of breath, dizziness, fainting, palpitations, anemia and edema, and blood clots which can increase the likelihood of stroke or pulmonary embolism. Symptoms can often be severe enough to be debilitating and/or life threatening.

In particular, a large portion or percentage of degenerative regurgitation in a mitral valve is caused by a prolapsed posterior mitral leaflet. This can be caused by weakening or separation of the chordae attached to the posterior leaflet. In such cases, when the mitral valve is in the closed configuration, the posterior mitral leaflet billows or bulges like a sail or a parachute into the left atrium, causing the posterior leaflet to not fully coapt with the anterior mitral leaflet.

Currently, treatment options for the repair of a prolapsing leaflet includes re-sectioning of the prolapsed tissue, chordae repair, foldoplasty, annuloplasty, placement of a new valve, or attachment of a clip to couple a free end of the prolapsing leaflet to a free end of a non-prolapsing leaflet. However, these solutions have significant drawbacks in terms of efficacy, safety or likelihood of complications, invasiveness, reduction in the cross-sectional area for blood flow through the valve, and the availability of the valve for future treatments.

Accordingly, there is a need for systems that can repair a valve suffering from regurgitation due to a prolapsing leaflet more easily, with greater efficacy and fewer complications. Further, there is a need for systems that can repair a valve suffering from regurgitation due to a prolapsing leaflet while leaving the valve available for future treatments.

### BRIEF SUMMARY OF THE INVENTION

Embodiments hereof are directed to a system for treating a valvular regurgitation in a heart valve. The system includes a flexible canopy and an elongated tether. A proximal end of the elongated tether is attached to a distal end of the flexible canopy. The flexible canopy includes a first surface and a second surface opposite the first surface. The elongated tether is configured to be placed under tension in situ and includes an inelastic portion and an elastic portion that is at least as long as the inelastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of a heart valve and a distal end of the elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

In another embodiment hereof, the system includes a flexible canopy and an elongated tether. A proximal end of the elongated tether is attached to a distal end of the flexible canopy. The flexible canopy includes a first surface and a second surface opposite the first surface. The flexible canopy is unsupported and does not include a frame attached thereto. The elongated tether is configured to be placed under tension in situ and includes an inelastic portion and an elastic portion. When the system is in a deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of a heart valve and a distal end of the elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

3

Embodiments hereof are further directed to a method of treating a valvular regurgitation. The method includes percutaneously delivering a system in a delivery configuration to a heart valve. The system includes a flexible canopy and an elongated tether attached to a distal end of the flexible canopy. The flexible canopy is unsupported and does not include a frame coupled thereto and the elongated tether includes an inelastic portion and an elastic portion that is at least as long as the inelastic portion. At least one proximal anchor is embedded into an annulus of the heart valve. A proximal end of the flexible canopy is coupled to the at least one proximal anchor. A distal anchor is embedded into a ventricle adjacent to the heart valve. A distal end of the elongated tether is coupled to the distal anchor. A tension force is applied on the flexible canopy such that a first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve. The heart valve is checked for regurgitation. The tension force on the flexible canopy is adjusted to minimize valvular regurgitation.

#### BRIEF DESCRIPTION OF DRAWINGS

The foregoing and other features and aspects of the present technology can be better understood from the following description of embodiments and as illustrated in the accompanying drawings. The accompanying drawings, which are incorporated herein and form a part of the specification, further serve to illustrate the principles of the present technology. The components in the drawings are not necessarily to scale.

FIG. 1 is a schematic sectional illustration of a mammalian heart having native valve structures.

FIG. 2A is a schematic sectional illustration of a left ventricle of a mammalian heart showing anatomical structures and a native mitral valve.

FIG. 2B is a schematic sectional illustration of the left ventricle of a heart having a prolapsed mitral valve in which the leaflets do not sufficiently coapt and which is suitable for repair with a system in accordance with embodiments hereof.

FIG. 2C is a schematic sectional illustration of the left ventricle of FIG. 2B as viewed from a different angle.

FIG. 2D is a top view illustration of the prolapsed mitral valve of FIG. 2B, wherein the mitral valve is in an open configuration.

FIG. 3A is a perspective illustration of a system for treating heart valvular regurgitation in accordance with an embodiment hereof.

FIG. 3B is a perspective illustration of the system of FIG. 3A and an anterior leaflet of a native mitral valve.

FIG. 4 is a schematic sectional illustration of a heart, wherein the system of FIG. 3A is implanted within the heart in a deployed configuration and a native mitral valve of the heart is in the open configuration.

FIG. 5 is a schematic sectional illustration of the heart, wherein the system of FIG. 3A is implanted within the heart in a deployed configuration and the native mitral valve of the heart is in a closed configuration.

FIG. 6 is a top view illustration of the mitral valve of FIG. 5, wherein the mitral valve is in the closed configuration.

FIG. 7A is a perspective illustration of a system for treating heart valvular regurgitation in accordance with another embodiment hereof.

FIG. 7B is a perspective illustration of a system for treating heart valvular regurgitation in accordance with yet another embodiment hereof.

4

FIG. 8 is a sectional cut-away illustration of a heart illustrating a method step of using the system of FIG. 3A to repair a prolapsed posterior leaflet of a native mitral valve using a transseptal approach in accordance with an embodiment hereof, wherein the system of FIG. 3A is shown in the delivery configuration within a delivery catheter positioned within the left atrium of the heart.

FIG. 9 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a plurality of proximal anchors is deployed to engage tissue at the annulus of the native mitral valve.

FIG. 10 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a proximal end of a flexible canopy of the system is coupled to the plurality of proximal anchors at the annulus of the native mitral valve.

FIG. 11 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a distal anchor is deployed to engage tissue in a left ventricle of the heart.

FIG. 12 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a distal end of an elongated tether of the system is coupled to the distal anchor in the left ventricle.

FIG. 13 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the native mitral valve, wherein a tension of the elongated member is applied such that the flexible canopy overlays the posterior leaflet of the native mitral valve.

FIG. 14 is a sectional cut-away illustration of the heart illustrating a method step of using the system of FIG. 3A to repair the prolapsed posterior leaflet of the mitral valve, wherein the tension of the elongated tether is adjusted to minimize regurgitation at the mitral valve.

#### DETAILED DESCRIPTION OF THE INVENTION

Specific embodiments of the present invention are now described with reference to the figures, wherein like reference numbers indicate identical or functionally similar elements. The terms “distal” and “proximal”, when used in the following description to refer to a delivery device, delivery system, or delivery catheter are with respect to a position or direction relative to the treating clinician. Thus, “distal” and “distally” refer to positions distant from, or in a direction away from the treating clinician, and the terms “proximal” and “proximally” refer to positions near, or in a direction toward the clinician. The terms “distal” and “proximal”, when used in the following description to refer to a system or a device to be implanted into a vessel, such as a system for treating heart valvular regurgitation, are used with reference to the direction of blood flow. Thus, “distal” and “distally” refer to positions in a downstream direction with respect to the direction of blood flow, and the terms “proximal” and “proximally” refer to positions in an upstream direction with respect to the direction of blood flow.

The following detailed description is merely exemplary in nature and is not intended to limit the present technology or the application and uses of the present technology. Although the description of embodiments hereof is in the context of treatment of heart valvular regurgitation and particularly in

the context of treatment of regurgitation of the mitral valve, the present technology may also be used in any other body passageways where it is deemed useful. Furthermore, there is no intention to be bound by any expressed or implied theory presented in the preceding technical field, background, brief summary or the following detailed description.

FIGS. 1-2D will now be described to provide contextual information on valve regurgitation. FIG. 1 is a schematic sectional illustration of a mammalian heart HE that depicts the four heart chambers (right atrium RA, right ventricle RV, left atrium LA, left ventricle LV) and native valve structures (tricuspid valve TV, mitral valve MV, pulmonary valve PV, aortic valve AV). FIG. 2A is a schematic sectional illustration of a left ventricle LV of a mammalian heart HE showing anatomical structures and a native mitral valve MV. Referring to FIGS. 1 and 2A together, the heart HE comprises the left atrium LA that receives oxygenated blood from the lungs via the pulmonary veins. The left atrium LA pumps the oxygenated blood through the mitral valve MV and into the left ventricle LV during ventricular diastole. The left ventricle LV contracts during systole and blood flows outwardly through the aortic valve AV, into the aorta and to the remainder of the body.

In a healthy heart, the mitral valve MV includes an open configuration and a closed configuration. When the mitral valve MV is in the open configuration, an anterior leaflet AL and a posterior leaflet PL do not coapt, permitting blood to flow from the right atrium RA to the left ventricle LV. When the mitral valve is in the closed configuration, as shown in FIG. 2A, the anterior and posterior leaflets AL, PL of the native mitral valve MV meet evenly at the free edges or “coapt” to close and prevent back flow of blood into the left atrium LA during contraction of the left ventricle LV. The tissue of the anterior and posterior leaflets AL, PL attach to the surrounding heart structure via a dense fibrous ring of connective tissue called an annulus AN which is distinct from both the tissue of the anterior and posterior leaflets AL, PL as well as the adjoining muscular tissue of the heart wall. In general, the connective tissue at the annulus AN is more fibrous, tougher and stronger than leaflet tissue. The flexible tissue of the anterior and posterior leaflets AL, PL of the native mitral valve MV are connected to papillary muscles PM, which extend upwardly from the lower wall of the left ventricle LV and the interventricular septum IVS, via branching tendons called chordae tendinae CT.

In a heart HE having a mitral valve MV experiencing valvular regurgitation due to a prolapsing first or posterior leaflet PL and a second or anterior leaflet AL, the respective edges of the posterior leaflet PL and the anterior leaflet AL do not sufficiently coapt or meet, as shown in FIGS. 2B-2D and leakage from the left ventricle LV into the left atrium LA will occur through a gap GP. Several structural defects can cause the mitral leaflets LF to prolapse, and subsequent regurgitation to occur, including ruptured chordae tendinae CT, impairment of papillary muscles PM (e.g., due to ischemic heart disease), and enlargement of the heart and/or mitral valve annulus AN (e.g., cardiomyopathy).

Embodiments of systems and associated methods in accordance with the present technology are described with reference to FIGS. 3A-14. It will be appreciated that specific elements, substructures, uses, advantages, and/or other aspects of the embodiments described herein and with reference to FIGS. 3A-14 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology.

Provided herein are systems and methods suitable for repairing a prolapsing leaflet of a heart valve to reduce or eliminate valvular regurgitation. More specifically, in embodiments hereof, a flexible canopy of the system is placed over an existing native leaflet of the heart valve and tensioned with an elongated tether to prevent leaflet prolapse and subsequent regurgitation resulting from the prolapsing leaflet. The system is adjustable via the elongated tether to set the system to minimize or eliminate valvular regurgitation. Further, the system may be readjusted during the initial procedure or in a subsequent procedure or procedures to account for changes in the native anatomy over time. The systems described herein do not reduce or alter the cross-sectional area of the native mitral valve and thus reduced blood flow through the heart valve is avoided and easy access to the heart valve is still permitted for future therapies and treatments.

Turning now to FIG. 3A, FIG. 3A is a perspective view of a system 100 for treating valvular regurgitation in a heart valve due to a prolapsing leaflet and configured in accordance with an embodiment hereof. The system 100 includes a flexible canopy 102 and an elongated tether 104. Further, the system 100 includes a delivery configuration, wherein the system is compressed for percutaneous delivery within a delivery catheter to a desired treatment location, and a deployed configuration, which is shown in FIG. 3A. When the system 100 is in the delivery configuration, the flexible canopy 102 can be folded, rolled, or otherwise compressed. The method of compressing the flexible canopy 102 is selected based upon a variety of characteristics including, but not limited to the order or sequence of anchor fixation or deployment.

As shown in FIG. 3A, the flexible canopy 102 is formed of a flexible material and includes a proximal end 106, a distal end 108 opposite the proximal end 106, an underside or first surface 114 and a top or second surface 116 opposite the first surface 114. The flexible canopy 102 may be formed of materials which will bond to the prolapsing leaflet via growth such as, but not limited to Dacron®, pericardial tissue, or other suitable materials. The proximal end 106 of the flexible canopy 102 is configured to be anchored in situ at or on an annulus of the heart valve. As used herein, “at or on” an annulus means at or on a level of a plane of the annulus of the native heart valve, including disposition at or on a level of an upper surface of the annulus or other superior levels of the valve. Further, when the system 100 is in the deployed configuration, the flexible canopy 102 is configured to overlay an underlying or concealed portion of a prolapsing leaflet of the native heart valve such that the first surface 114 abuts against or contacts the underlying portion of the prolapsing leaflet, as described in more detail below. The flexible nature of the flexible canopy 102 permits the flexible canopy 102 to conform to the shape of the native prolapsing leaflet as best shown in FIG. 3B. FIG. 3B shows the system 100 with the flexible canopy 102 thereof overlaying and conforming to a native posterior leaflet PL, with the flexible canopy 102 coapting with a native anterior leaflet AL of a native heart valve. As used herein, the term “conform” means that the flexible canopy 102 assumes the same shape, outline, or contour of the underlying anatomy of the native prolapsing leaflet such that the flexible canopy 102 maintains consistent and close contact with the native prolapsing leaflet adjacent thereto. Thus, while the flexible canopy 102 of FIG. 3A is shown with a particular shape, this is by way of example and not limitation, and it will be understood that the flexible canopy 102 assumes or conforms to the shape of the native prolapsing leaflet. Such

conformability is required in order for the system **100**, and more particularly the flexible canopy **102** to prevent the native leaflet from prolapsing when the system **100** is in the deployed configuration as described in greater detail below. Over time, due to the material of the flexible canopy **102**, the first surface **114** of the flexible canopy **102** bonds or fuses to the underlying first surface of the prolapsing leaflet.

In the embodiment of FIG. 3A, the first surface **114** of the flexible canopy **102** includes a plurality of micro-tines or micro-barbs **110** configured to aid in coupling the first surface **114** of the flexible canopy **102** to the underlying first surface of the native prolapsing leaflet. While shown in FIG. 3A with three (3) micro-barbs **110**, this is by way of example and not limitation and more or fewer micro-barbs **110** may be used. In an embodiment, the micro-barbs **110** may have a diameter in a range of between about 0.005 inches and about 0.010 inches, and the length of the micro-barbs **110** may be in a range of between about 0.010 inches and about 0.100 inches. The micro-barbs **110** may be shaped to embed into an adjacent surface such as, but not limited to, a wedged shape where the tip of the wedge comes in contact with the adjacent surface. In another embodiment, the micro-barbs **110** may be a series of metallic wires.

In the embodiment depicted in FIGS. 3A and 3B, the flexible canopy **102** is unsupported. Stated another way, in the embodiment depicted in FIGS. 3A and 3B, the flexible canopy **102** does not include a support frame and consists only of the flexible material that has the first surface **114** and the opposing second surface **116**. As used herein, “unsupported” means that the flexible canopy has no radial or longitudinal support along its length and is not attached to a scaffold or frame structure. Due to the unsupported nature thereof, the flexible canopy **102** is permitted to conform to the underlying leaflet structure and further is non-traumatic to the surrounding native anatomy.

The size and perimeter of the flexible canopy **102** may be selected based upon the desired amount of leaflet coverage, the shape of the native anatomy, and/or desired anchoring positions. As best shown in FIG. 3B, in an embodiment hereof, the flexible canopy **102** has an oblong shape and is configured to overlay the prolapsing leaflet of the native heart valve such that the first surface **114** of the flexible canopy is in contact with substantially the entire underlying surface (i.e., at least 90%) of the prolapsing leaflet of the native heart valve. In another embodiment hereof, the flexible canopy **102** is configured to overlay the prolapsing leaflet of the native heart valve such that the first surface **114** of the flexible canopy is in contact with between forty and ninety percent (40-90%) of the underlying surface of the prolapsing leaflet of the native heart valve. In addition, while the flexible canopy **102** of FIGS. 3A and 3B is shown with a particular length that extends distally a particular distance, this is by way of example and not limitation, and it will be understood that other lengths that are suitable to treat valvular regurgitation may be used. More particularly, as best shown in FIG. 3B, in an embodiment the flexible canopy **102** extends distally beyond a distal end of the native posterior leaflet PL. However, in an alternative embodiment, the flexible canopy **102** does not extend beyond a prolapsing portion of the posterior leaflet PL. It will be understood that the shape and size of the flexible canopy **102** may assume any and all possible permutations including, but not limited to the flexible canopy **102** spanning most of the native prolapsing leaflet, spanning just past the prolapsing portion of the native prolapsing leaflet or any other configurations suitable for the purposes described herein.

The elongated tether **104** will now be described in more detail with reference to FIG. 3A. The elongated tether **104** has a first length L1 extending from a proximal end **120** thereof, which is attached to the distal end **108** of the flexible canopy **102**, to a distal end **122** thereof. The proximal end **120** of the elongated tether **104** may be coupled to the distal end **108** of the flexible canopy **102** by methods including but not limited to adhesives, tying, sutures, mechanical devices, fusing, or any other method suitable for the purposes described herein. The elongated tether **104** includes an elastic portion **124** coupled to an inelastic portion **126**. The elastic portion **124** is an elongate member having elastic qualities. As used herein, “elastic” means that the elongate member returns or is able to resume its original length or shape after distortion. The elastic portion **124** may be formed of elastic materials such as, but not limited to prosthetic chordae materials such as silicone, gore, Gore-tex®, or any other suitable material. When the system **100** is in the deployed configuration in situ, the elastic portion **124** is configured to allow for dynamic movement of the flexible canopy **102**. The inelastic portion **126** is an elongate member having inelastic qualities. As used herein, “inelastic” means that the elongate member **126** is not elastic and cannot be stretched. The inelastic portion **126** may be formed of inelastic materials such as, but not limited to a monofilament or plastic suture materials such as polypropylene, metal alloys such as stainless steel, titanium, or nickel-titanium alloys (i.e. NITINOL), or any other suitable material.

The elongated tether **104** is continuous or stated another way, the elastic portion **124** and the inelastic portion **126** collectively form the elongated tether **104**. The elastic portion **124** includes a proximal end **128** and a distal end **130**, while the inelastic portion **126** includes a proximal end **132** and a distal end **134**. In the embodiment of FIGS. 3-6, the elastic portion **124** is disposed proximal of the inelastic portion **126**. More specifically, the proximal end **128** of the elastic portion **124** is coupled to the distal end **108** of the flexible canopy **102** and the distal end **130** of the elastic portion **124** is coupled to the proximal end **132** of the inelastic portion **126**. The proximal end **132** of the inelastic portion **126** may be coupled to the distal end **130** of the elastic portion **124** by methods including, but not limited to adhesives, tying, sutures, mechanical devices, fusing, or any other method suitable for the purposes described herein. The ratio of the elastic portion **124** to the inelastic portion **126** with reference to the first length L1 of the elongated tether **104** is selected based on a variety of characteristics including, but not limited to the native valve location, the native anatomy, and the characteristics and geometry of the system **100**. In an embodiment hereof, as shown in FIGS. 3A and 3B, the elastic portion **124** is longer than the inelastic portion **126** to ensure that dynamic movement of the flexible canopy **102** is permitted in situ. For example, the ratio of the elastic portion **124** to the inelastic portion **126** of the elongated tether **104** may be 50/50, 60/40, 70/30, or other ratio found suitable for repairing valvular regurgitation.

The distal end **122** of the elongated tether **104** is coupled to a distal anchor (not shown in FIG. 3A) which is anchored in a ventricle adjacent the prolapsing valve. The elongated tether **104** is configured to be placed into tension when the system **100** is in the deployed configuration and implanted in situ, as described in more detail below. When placed into tension, the elongated tether **104** pulls on the distal end **108** of the flexible canopy **102** in a distal direction as indicated by a directional arrow **150**. Stated another way, when the elongated tether **104** is placed into tension during implan-

tation, the elongated tether **104** places the flexible canopy **102** into tension. Further, the tension on the elongated tether **104** is configured to be adjustable in situ to adjust or tune the curvature of the flexible canopy **102** and/or the angle at which the flexible canopy **102** coapts with the non-prolapsing leaflet or leaflets of the heart valve to minimize or reduce regurgitation. When the tension applied to the elongated tether **104** is increased, the elastic portion **124** of the elongated tether **104** stretches or elongates and the first length **L1** of the elongated tether **104** relatively increases. Conversely, when the tension applied to the elongated tether **104** is decreased, the elastic portion **124** of the elongated tether **104** shortens and the first length **L1** of the elongated tether **104** relatively decreases. Devices and methods for placing the elongated tether **104** into tension will be discussed in more detail with respect to FIG. **4** below.

The interaction of the components of the system **100** will now be described with reference to FIGS. **4-6**. FIGS. **4** and **5** are schematic sectional illustrations of the system **100** in a deployed configuration implanted within a heart HE, with FIG. **4** illustrating a native mitral valve MV of the heart in an open configuration and FIG. **5** illustrating the native mitral valve MV of the heart HE in a closed configuration. FIG. **6** is a top view illustration of the native mitral valve MV of the heart HE in the closed configuration. Within FIGS. **4-6**, the direction of blood flow is indicated by arrows BF. The system **100** is configured to repair a prolapsing posterior leaflet PL of the mitral valve MV. More particularly, when the system **100** is in the deployed configuration and implanted within the heart HE, the proximal end **106** of the flexible canopy **102** is anchored or coupled to an annulus AN of the mitral valve MV by at least one proximal anchor **136**. The first surface **114** of the flexible canopy **102** overlays and is in contact with an underlying first surface of the first or posterior leaflet PL of the mitral valve MV. The elongated tether **104** extends from the distal end **108** of the flexible canopy **102** to a distal anchor **138** in the left ventricle LV.

The proximal and distal anchors **136**, **138** may be of any anchor suitable for embedding into the tissue of the annulus AN and the left ventricle LV, respectively, including but limited to helical screws or anchors, barbs, or clips. In the embodiment illustrated in FIGS. **4** and **5**, each of the proximal anchors **136** and the distal anchor **138** are shown as helical screws or anchors. Each helical anchor **136**, **138** is rotatable by a corresponding releasable shaft of a delivery catheter to embed the respective helical anchor in myocardial tissue. For example, and not by way of limitation, each of the proximal and distal anchors **136**, **138** may be an anchor as described in U.S. Pat. No. 3,974,834 to Kane or U.S. Pat. No. 4,046,151 to Rose, each of which is assigned to the same assignee of the present invention and each of which is hereby incorporated by reference in its entirety herein. While described herein as helical anchors **136**, **138**, this is by way of example and not limitation and the shape of the proximal and distal anchors **136**, **138** may have other shapes and other methods for delivery. For example, and not by way of limitation, the proximal and/or distal anchors **136**, **138** may be an anchor as described in U.S. Pat. No. 4,341,226 to Peters or U.S. Pat. No. 9,775,982 to Grubac et al., each of which is assigned to the same assignee of the present invention and each of which is hereby incorporated by reference in its entirety herein.

As described above, when the system **100** is in the deployed configuration and implanted in situ as shown in FIG. **4**, the elongated tether **104** is placed into tension in order to properly position the flexible canopy **102** to overlay the underlying first surface of the first or posterior leaflet PL

of the mitral valve MV. In an embodiment hereof, the distal end **122** of the elongated tether **104** is pre-attached to the distal anchor **138** and the elongated tether **104** is placed into tension by attaching the distal anchor **138** to the left ventricle LV in such a way that provides tension to the elongated tether **104**. More particularly, tension is provided to the elongated tether **104** by varying the amount that the distal anchor **138** is advanced or embedded into a wall of the left ventricle LV. For example, when the distal anchor **138** is a helical screw as shown, the distal anchor **138** may be screwed into the wall of the left ventricle LV a greater amount or distance to increase the tension applied to the elongated tether **104**. Conversely, the distal anchor **138** may be unscrewed to decrease the tension applied to the elongated tether **104**, if desired. In another embodiment hereof, the distal end **122** of the elongated tether **104** is pre-attached to the distal anchor **138**, and the elongated tether **104** is placed into tension by varying the angle at which the elongated tether **104** extends from the flexible canopy **102**. More particularly, the location of the distal anchor **138** may be moved to increase or decrease the angle at which the elongated tether **104** extends from the flexible canopy **102**. For example, the location of the distal anchor **138** may be moved towards the apex AP of the left ventricle LV to increase the tension applied to the elongated tether **104**. Conversely, the location of the distal anchor **138** may be moved towards the interventricular septum IVS of the left ventricle LV to decrease the tension applied to the elongated tether **104**.

In another embodiment hereof, the elongated tether **104** is configured to be placed into tension via a tensioning device or tensioner (now shown). For example, a tensioning device as described in U.S. Pat. No. 9,452,048 to O'Bierne et al., assigned to the same assignee of the present invention and which is hereby incorporated by reference in its entirety herein, may be modified and utilized as a tensioning device or tensioner. For example, the elongated tether **104** may initially be slidably coupled to the distal anchor **138** via an integral loop of the elongated tether **104** such that a free end of the elongated tether **104** extends proximally through a delivery catheter and is accessible to the physician. After the distal anchor **138** is secured to the wall of the ventricle, the physician may pull on the accessible free end of the elongated tether **104** to effectively decrease the first length **L1** of the elongated tether **104** in situ and further effectively increase the tension placed on the elongated tether **104**. Conversely, the physician may release or push the free end of the elongated tether **104** to effectively increase the first length **L1** of the elongated tether **104** in situ and further effectively decrease the tension placed the elongated tether **104**. Once the tension is optimized, a locking mechanism as described in U.S. Pat. No. 9,452,048 to O'Bierne et al., previously incorporated by reference above, may be slid or advanced over the free end of the elongated tether **104** and through the delivery catheter until the locking mechanism abuts against the distal anchor **138** and thereby secures the position of the elongated tether **104** being placed under the desired amount of tension. Any excess length of the elongated tether **104**, i.e., the length of tether extending from the locking mechanism to the free end extending proximally back to the physician, may be cut and removed from the patient. A tensioning device has been described herein by way of example and not limitation. It will be understood that the tensioning device may be any suitable device configured to permit the elongated tether **104** to be placed into tension, and more specifically to adjust or change the first length **L1**

of the elongated tether **104** to increase or decrease the amount of tension placed onto the elongated tether **104** as described above.

Regardless of which method or device is used to place the elongated tether **104** into tension, the first length **L1** of the elongated tether **104** is varied during adjustment of the tension placed on the elongated tether **104**. Accordingly, when the first length **L1** of the elongated tether **104** is reduced to increase the tension placed on the elongated tether **104**, the elastic portion **124** thereof is stretched. Because of the desire of the elastic portion **124** to return to its resting shape or length, the elastic portion **124** is placed into spring tension. This spring tension is transferred to adjacent coupled components as a tension force. More precisely, the spring tension pulls on the proximal end **132** of the inelastic portion **126** and is transferred through the inelastic portion **126** to the distal end **122** of the elongated tether **104** anchored to the left ventricle **LV** by the distal anchor **138** with a first tension force represented by a directional arrow **TF1** illustrated in FIG. **5**. Further, the spring tension pulls on the distal end **108** of the flexible canopy **102** and is transferred through the flexible canopy **102** to the proximal end **106** of the flexible canopy **102** anchored at the annulus **AN** by the at least one proximal anchor **136** with a second tension force represented by a directional arrow **TF2** illustrated in FIG. **5**. For the purposes described herein, the distal anchor **138** and the at least one proximal anchor **136** are stationary relative to the system **100**. It will be understood that the first and second tension forces **TF1** and **TF2** are equal and opposite. The distal end **108** of the flexible canopy **102** is pulled in the direction of the arrow **TF2** with sufficient tension force that the flexible canopy **102**, or more precisely the first surface **114** thereof is placed into contact with the underlying first surface of the posterior leaflet **PL**, and thereby prevents the posterior leaflet **PL** from prolapsing. Further, the tension force on the flexible canopy **102** may be adjusted to optimize coaptation of the flexible canopy **102** with the second leaflet of the heart valve, and to minimize valvular regurgitation. Stated another way, the tension force on the elongated tether **104** is adjustable to maximize coaptation of a portion of the second surface **116** of the flexible canopy **102** with an opposing mating portion of an anterior leaflet **AL** of the mitral valve **MV**, and to minimize or eliminate regurgitation at the mitral valve **MV**.

While shown with three proximal anchors **136** in specific locations in FIG. **6**, this is by way of example and not limitation. It will be understood that more or fewer proximal anchors **136** may be used, and that the proximal anchor(s) **136** may be disposed at other locations. Further, while the distal anchor **138** is shown in FIG. **5** disposed at the apex **AP** of the left ventricle **LV**, this too is by way of example and not limitation. The distal anchor **138** may be disposed at any location within the left ventricle **LV** to optimize an angle between the coapting surfaces of the flexible canopy **102** and the anterior leaflet **AL**. For example, the distal anchor **138** may be disposed at any location within the left ventricle **LV** including, but not limited to the apex **AP**, the ventricle wall, the interventricular septum **IVS**, or the papillary muscle **PM**.

FIG. **7A** is a perspective view of a system **200** for treating regurgitation of a heart valve due to a prolapsing leaflet and configured in accordance with another embodiment hereof. The system **200** includes a flexible canopy **202** and an elongated tether **204**, the elongated tether **204** including an elastic portion **224** and an inelastic portion **226**. In the embodiment in FIG. **7A**, the flexible canopy **202** includes a

frame **242** and the elongated tether **204** has an alternative configuration than the elongated tether **104** described above.

As shown in FIG. **7A**, the flexible canopy **202** is formed of a flexible material and is similar to the flexible canopy **102** previously described. Therefore, similar details of the configuration and materials of the flexible canopy **202** will not be repeated. However, the flexible canopy **202** is supported by a frame **242** coupled to the material of the flexible canopy **202**. The frame **242** is disposed at a proximal portion **248** of the flexible canopy **202**. In the embodiment of FIG. **7A**, the frame **242** has a D-shaped configuration and a first or curved end portion **244** of the frame **242** is disposed adjacent a proximal end **206** of the flexible canopy **202**. The frame **242** is disposed adjacent to a perimeter of the flexible canopy **202** and the frame **242** further generally follows the shape of the perimeter of the flexible canopy **202**. However, this is not meant to be limiting, and it will be understood that the frame **242** may be disposed at any location of the flexible canopy **202**. In embodiments hereof, the frame **242** is configured to provide structural support to a proximal portion **248** of the flexible canopy **202**. Further, the frame **242** serves to maintain coaptation angles between the flexible canopy **202** and the non-prolapsing leaflet or leaflets of the heart valve when the system **200** is in a deployed configuration and the heart valve is in a closed configuration. While shown with a specific shape, the frame **242** may have other shapes including but not limited to an ellipse, a circle, or any other shape suitable for the purposes described herein. Further, embodiments of the frame **242** may include additional struts or other strengthening members. The frame **242** may be formed of materials such as, but not limited to nickel titanium alloys (e.g. **NITINOL**), stainless steel, or other suitable materials. The frame **242** may be sewn into the flexible canopy **202** or may be coupled to the flexible canopy **202** by any other suitable method. In an embodiment, the frame **242** is attached to a plurality of proximal anchors **236**.

In the embodiment of FIG. **7A**, the frame **242** is configured to be disposed only on the atrial side of the native mitral valve when the system **200** is in a deployed configuration in situ. When the frame **242** is disposed only on the atrial side of the native mitral valve, the flexible canopy **202** is permitted to have increased flexibility within the left ventricle. Further, with the frame **242** disposed only on the atrial side of the native mitral valve, there are no relatively rigid or stiff elements of the frame **242** within the left ventricle **LV** that have potential to damage the chordae or other native anatomy within the left ventricle **LV**. In an alternate embodiment, the frame **242** may extend distally into the adjacent ventricle.

The elongated tether **204** of FIG. **7A** is similar to the elongated tether **104** of FIG. **3A**, except that the configuration or arrangement of the elastic and inelastic portions **224**, **226**, respectively are reversed from the configuration of the elongated tether **104** shown in FIG. **3A**. More particularly, in the embodiment of FIG. **7A**, the elastic portion **224** is disposed distal of the inelastic portion **226**. The elastic portion **224** includes a proximal end **228** and a distal end **230**. In the embodiment of FIG. **7A**, the elastic portion **224** is a helical spring. As with the elastic portion **124** of FIG. **3A**, the elastic portion **224** is configured to impart a tension force on the flexible canopy **202** as previously described with respect to the elastic portion **124** of FIG. **3A**, and therefore is not described in detail with respect to FIG. **7A**.

The configuration of the inelastic portion **226** of the elongated tether **204** of FIG. **7A** includes a proximal end **232** coupled to the distal end **208** of the flexible canopy **202**, a distal end **234** of the inelastic portion **226** coupled to the

proximal end **228** of the elastic portion **224**, and the distal end **230** of the elastic portion **224** coupled to the ventricle as previously described with respect to the distal end **134** of FIGS. 4-6. While the inelastic portion **226** and the elastic portion **224** are positioned at opposite ends of the elongated tether **204** than the elastic portion **124** and the inelastic portion **126** of the elongated tether **104** of FIG. 3A, it will be understood that applying and adjusting the tension force on the flexible canopy **202** is similarly accomplished by lengthening or shortening the length of the elongated tether **204**.

While described herein with one (1) spring elastic portion **224**, in an alternative embodiment, an elongated tether **204'** includes two (2) spring elastic portions **224a** and **224b**, disposed at the proximal end **232'** and the distal end **234'**, respectively, of the inelastic portion **226'**, as shown in FIG. 7B. The two spring elastic portions **224a** and **224b** help to ensure that dynamic movement of the flexible canopy **202** is permitted in situ.

FIGS. 8-14 are sectional cut-away views of a heart HE illustrating method steps of treating regurgitation at a mitral valve MV via a transeptal approach for delivering and deploying the system **100** of FIG. 3 in accordance with an embodiment hereof. Access to the mitral valve MV can be accomplished through a patient's vasculature in a percutaneous manner. In an embodiment, the approach to the mitral valve is antegrade and may be accomplished via entry into the left atrium by crossing the interatrial septum. As is known in the art, a guidewire (not shown) may be advanced intravascularly using any number of techniques, e.g., through the inferior vena cava or superior vena cava (FIG. 1), into the right atrium RA through a penetration hole cut in the inter-atrial septum (not shown) and into the left atrium LA (FIG. 1). A guide catheter (not shown) may be advanced along the guidewire and into the right atrium RA, through the penetration hole in the inter-atrial septum, and into the left atrium LA. The guide catheter may have a pre-shaped or steerable distal end to shape or steer the guide catheter such that it will direct a delivery catheter toward the mitral valve MV.

Alternatively, the mitral valve may also be accessed via a transatrial approach for e.g., directly through an incision in the left atrium LA. Access to the heart may be obtained through an intercostal incision in the chest without removing ribs, and a guiding catheter (not shown) may be placed into the left atrium LA through an atrial incision sealed with a purse-string suture. A delivery catheter may then be advanced through the guiding catheter to the mitral valve. Alternatively, the delivery catheter may include a guidewire lumen such that it may be tracked over a guidewire and placed directly through the atrial incision without the use of a guiding catheter.

Referring to FIG. 8, a distal segment **303** of a delivery catheter **301** is shown positioned in the left atrium LA. The delivery catheter **301** is delivered through the vasculature into the left atrium LA with the system **100** in a delivery configuration, in which the system **100** is radially compressed and disposed within the distal segment **303** of the delivery catheter **301**. Intravascular access to the right atrium RA may be achieved via a percutaneous access site in a femoral, brachial, radial, or axillary artery. As will be understood by those knowledgeable in the art, a handle component (not visible in FIGS. 8-14), as well as some length of a proximal segment of the delivery catheter **301**, are exposed externally of the patient for access by a clinician. By manipulating the handle of the delivery catheter **301** from outside the vasculature, a clinician may advance

and remotely manipulate and steer the distal segment **303** of the delivery catheter **301** through the sometimes tortuous intravascular path. The distal segment **303** of the delivery catheter **301** may be distally advanced into the left atrium LA and positioned generally above (e.g., upstream) the mitral valve MV to deliver the system **100** to the mitral valve MV.

In a next delivery step shown in FIG. 9, three proximal anchors **136** are embedded in tissue at an annulus AN of the mitral valve MV. Embedding of each proximal anchor **136** at the annulus AN may be accomplished by various methods understood by those knowledgeable in the art. For example, and not by way of limitation, each proximal anchor **136** may be a helical anchor, rotated by a respective proximal anchor shaft **305** of the delivery catheter **301** to embed each proximal anchor **136** into tissue at the annulus AN. Each proximal anchor shaft **305** may be a shaft, rod, or lead as described, for example, in U.S. Pat. No. 3,974,834 or 4,046,151, each of which has previously been incorporated by reference in its entirety. Once each proximal anchor **136** is embedded at the annulus AN, the proximal anchor **136** is released from the respective proximal anchor shaft **305**.

In the embodiment of FIG. 9, each proximal anchor **136** is pre-attached to the flexible canopy **102** prior to delivery with the delivery catheter **301**. Thus, once the proximal anchors **136** are embedded at the annulus AN and each proximal anchor **136** is released from the respective proximal anchor shaft **305**, the proximal end **106** of the flexible canopy **102** remains attached to each of the proximal anchors **136** at the annulus AN, as shown in FIG. 10. The proximal end **106** is attached to the plurality of proximal anchors **136** to effectively anchor or secure the proximal end **106** of the flexible canopy **102** to the annulus AN of the native mitral valve MV.

While described herein with the flexible canopy **102** pre-attached to the plurality of proximal anchors **136** prior to delivery by the delivery catheter **301**, this is by way of example and not limitation. It will be understood that the flexible canopy **102** can alternatively be coupled to the plurality of proximal anchors **136** after each of the proximal anchors **136** has been embedded at the annulus AN of the native mitral valve MV. For example, and not by way of limitation, the flexible canopy **102** may include a plurality of eyelets attached thereto with each proximal anchor shaft **305** disposed through a corresponding eyelet. The flexible canopy **102** can be deployed from the delivery catheter **301** by a push shaft or other device, and each eyelet and the flexible canopy **102** slide distally along the respective plurality of proximal anchor shafts **305** to couple to the corresponding proximal anchors **136**. Once the flexible canopy **102** is coupled to the plurality of proximal anchors **136**, each proximal anchor **136** is released by the respective proximal anchor shaft **305**.

As shown in FIG. 11, in a next step the distal anchor **138** is embedded in tissue within the left ventricle LV with a distal anchor shaft **307**. Embedding of the distal anchor **138** may be accomplished by various methods understood by those knowledgeable in the art. For example, and not by way of limitation, the distal anchor **138** may be a helical anchor, rotated by the distal anchor shaft **307** to embed the distal anchor **138** in an apex AP of the left ventricle LV. The distal anchor shaft **307** may be a shaft, rod, or lead as described, for example, in U.S. Pat. No. 3,974,834 or 4,046,151 assigned to Medtronic, Inc., each of which has previously been incorporated by reference in its entirety. While shown with the distal anchor **138** embedded in tissue at an apex AP of the left ventricle LV, this is by way of example and not

limitation. As previously described, the location of the distal anchor **138** within the left ventricle LV may be determined based upon the angle of the flexible canopy **102** in relation to the anterior leaflet AL to achieve optimal coaptation between the flexible canopy **102** and the anterior leaflet AL to minimize or eliminate regurgitation. Once the distal anchor **138** is embedded at the desired location of the left ventricle LV, the distal anchor **138** is released from the distal anchor shaft **307**.

In the embodiment of FIG. **11**, the distal anchor **138** is pre-attached to the elongated tether **104** prior to delivery with the delivery catheter **301**. Accordingly, once the distal anchor **138** is embedded in the left ventricle LV and the distal anchor **138** is released from the distal anchor shaft **307**, the distal end **122** of the elongated tether **104** is attached to the distal anchor **138**, as shown in FIG. **12**. The distal end **122** is attached to the distal anchor **138** to effectively secure or anchor the distal end **122** of the elongated tether **104** to the left ventricle LV.

Although the elongated tether **104** has been described as coupled to the distal anchors **138** prior to delivery by the delivery catheter **301**, this is by way of example and not limitation. It will be understood that the elongated tether **104** may alternatively be delivered separately and coupled to the distal anchor **138** after the distal anchor **138** has been embedded in the left ventricle LV. For example, and not by way of limitation, the elongated tether **104** can include an eyelet at the distal end **122** with the distal anchor shaft **307** disposed through the eyelet of the elongated tether **104**. The elongated tether **104** can be deployed from the delivery catheter **301** by a push shaft or other device, and the eyelet and the elongated tether **104** slid distally along the distal anchor shaft **307** to couple to the eyelet of the elongated tether **104** to the distal anchor **138**. Once the elongated tether **104** is coupled to the distal anchor **138**, the distal anchor **138** is released by the distal anchor shaft **307**.

When the proximal end **106** of the flexible canopy **102** is coupled to the annulus AN and the distal end **122** of the elongated tether **104** is coupled to the left ventricle LV, with the flexible canopy **102** overlaying the posterior leaflet PL, tension is applied and/or adjusted as described above with respect to FIGS. **4** and **5** to apply a tension force on the flexible canopy **102**. More precisely, as described above in more detail, the elastic portion **124** of the elongated tether **104** is placed under spring tension and the spring tension on the elastic portion **124** is transferred to the distal end **108** of the flexible canopy **102** as a second tension force TF2 as indicated by the arrow TF2. The second tension force TF2 on the flexible canopy **102** prevents the posterior leaflet PL from prolapsing and insures coaptation of the flexible canopy **102** with the anterior leaflet AL, as shown in FIG. **13**.

In a next step, the mitral valve MV is checked for valvular regurgitation. Checking for regurgitation of the mitral valve MV may be accomplished by various methods including, but not limited to echocardiogram, to visualize placement of the flexible canopy **102** and prolapse of the posterior leaflet PL of the mitral valve MV. Accordingly, an echogenic coating may be applied to one or more integral portions of the system **100** to aid in visualization. When the mitral valve MV has been checked for valvular regurgitation, the treating clinician may further adjust the tension force on the flexible canopy **102** to minimize valvular regurgitation and optimize coaptation of the flexible canopy **102** with the anterior leaflet AL, as shown in FIG. **14**. The steps of checking for valvular regurgitation and readjusting the tension force on the flexible canopy **102** may be repeated to optimize performance of the repaired mitral valve MV. Following delivery, deploy-

ment and adjustment of the system **100** at the mitral valve MV (or other desired valve location), the delivery catheter **301** and remaining guidewire (if any) may be removed from the heart **10** and out of the body of the patient.

Image guidance, enhanced echogenicity, or other methods may be used to aid the clinician's delivery and positioning of the system **100**. Image guidance, e.g., intracardiac echocardiography (ICE), fluoroscopy, computed tomography (CT), intravascular ultrasound (IVUS), optical coherence tomography (OCT), or another suitable guidance modality, or combination thereof, may be used to aid the clinician's positioning and manipulation of the system **100** at the target native valve region. For example, such image guidance technologies can be used to aid in determining the positioning of the flexible canopy **102** with relation to the underlying, prolapsing native leaflet. In some embodiments, image guidance components (e.g., IVUS, OCT) can be coupled to the distal portion of the delivery catheter **301**, a guide catheter, or both to provide three-dimensional images of the area proximate to the target heart valve region to facilitate positioning, orienting and/or deployment of the system **100** within the heart valve region. Accordingly, an echogenic coating may be applied to components of the system to aid in visualization.

Various method steps described above for delivery and deployment of embodiments of the system within a native heart valve of a patient may also be interchanged to form additional embodiments of the present technology. For example, while the method steps described above are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

Furthermore, while the delivery catheter described above is discussed as being suitable for delivering embodiments of the system to the native mitral valve using a transeptal approach, it will be understood that the delivery catheter may also be suitable for delivering systems for repair of other heart valves (e.g., pulmonary valve, tricuspid valve, etc.) and utilizing other approaches (e.g. retrograde, antegrade). Various arrangements of the delivery catheters suitable for use with embodiments of systems and methods described herein may also be used to deliver other therapeutic or medical tools within body lumens.

While various embodiments have been described above, it should be understood that they have been presented only as illustrations and examples of the present technology, and not by way of limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail may be made therein without departing from the spirit and scope of the present technology. Thus, the breadth and scope of the present technology should not be limited by any of the above-described embodiments, but should be defined only in accordance with the appended claims and their equivalents. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, may be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

What is claimed is:

1. A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:
  - a flexible canopy including a first surface and a second surface opposite the first surface;



17

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein the elastic portion is at least as long as the inelastic portion with a ratio of the elastic portion to the inelastic portion being between 50/50 and 70/30 and a proximal end of the elongated tether is attached to a distal end of the flexible canopy; and  
 a distal anchor configured to be embedded into tissue of a ventricle, wherein a distal end of the elongated tether is coupled to the distal anchor,  
 wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and the distal end of the elongated tether is anchored to tissue of a ventricle via the distal anchor such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

**2.** The system of claim **1**, wherein when the first surface of the flexible canopy overlays the first leaflet of the heart valve, the first surface of the flexible canopy is substantially in contact with between forty and ninety percent of the underlying first surface of the first leaflet of the heart valve.

**3.** The system of claim **1**, wherein the flexible canopy does not extend into the ventricle when the system is in the deployed configuration.

**4.** The system of claim **1**, wherein the inelastic portion of the elongated tether is positioned distal of the elastic portion of the elongated tether.

**5.** The system of claim **1**, wherein the elastic portion of the elongated tether is positioned distal of the inelastic portion of the elongated tether.

**6.** The system of claim **1**, wherein the elastic portion of the elongated tether is longer than the inelastic portion of the elongated tether.

**7.** The system of claim **1**, wherein the elastic portion of the elongated tether is a spring.

**8.** The system of claim **1**, further comprising: a frame coupled to a portion of the flexible canopy.

**9.** The system of claim **8**, wherein the frame does not extend into the ventricle when the system is in the deployed configuration.

**10.** The system of claim **1**, wherein the flexible canopy is unsupported and does not include a frame coupled thereto.

**11.** The system of claim **1**, wherein the flexible canopy extends into the ventricle when the system is in the deployed configuration.

**12.** A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:

a flexible canopy including a first surface and a second surface opposite the first surface; and

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein the elastic portion is at least as long as the inelastic portion and a proximal end of the elongated tether is attached to a distal end of the flexible canopy,

wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and a distal end of the

18

elongated tether is anchored to tissue of a ventricle such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve, and

wherein the first surface of the flexible canopy includes at least one micro-barb and the at least one micro-barb is configured to couple the first surface of the flexible canopy to the underlying first surface of the first leaflet of the heart valve.

**13.** A system for treating valvular regurgitation in a heart valve, the system including a delivery configuration and a deployed configuration, the system comprising:

a flexible canopy including a first surface and a second surface opposite the first surface, wherein the flexible canopy is unsupported and does not include a frame coupled thereto; and

an elongated tether configured to be placed under tension in situ, the elongated tether including an elastic portion and an inelastic portion coupled to the elastic portion, wherein a ratio of the elastic portion to the inelastic portion is between 50/50 and 70/30, and wherein a proximal end of the elongated tether is attached to a distal end of the flexible canopy; and

a distal anchor configured to be embedded into tissue of a ventricle, wherein a distal end of the elongated tether is coupled to the distal anchor,

wherein when the system is in the deployed configuration, a proximal end of the flexible canopy is anchored to an annulus of the heart valve and the distal end of the elongated tether is anchored to tissue of a ventricle via the distal anchor such that the first surface of the flexible canopy overlays an underlying first surface of a first leaflet of the heart valve, and the elongated tether is placed under tension such that the system is configured to prevent the first leaflet of the heart valve from prolapsing, and to permit a portion of the second surface of the flexible canopy to coapt with at least an opposing mating portion of a second leaflet of the heart valve.

**14.** The system of claim **13**, wherein when the first surface of the flexible canopy overlays the first leaflet of the heart valve, the first surface of the flexible canopy is substantially in contact with between forty and ninety percent of the underlying first surface of the first leaflet of the heart valve.

**15.** The system of claim **13**, wherein the first surface of the flexible canopy includes at least one micro-tine and the at least one micro-tine is configured to couple the first surface of the flexible canopy to the underlying first surface of the first leaflet of the heart valve.

**16.** The system of claim **13**, wherein the flexible canopy does not extend into the ventricle when the system is in the deployed configuration.

**17.** The system of claim **13**, wherein the flexible canopy extends into the ventricle when the system is in the deployed configuration.

**18.** The system of claim **13**, wherein the inelastic portion of the elongated tether is positioned distal of the elastic portion of the elongated tether.

**19.** The system of claim **13**, wherein the elastic portion of the elongated tether is positioned distal of the inelastic portion of the elongated tether.

20. The system of claim 13, wherein the elastic portion of the elongated tether is longer than the inelastic portion of the elongated tether.

\* \* \* \* \*